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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Environmental Statement 2023

Reporting on performance for 1 January to 31 December 2023

In accordance with EMAS Regulation Article 4 (1) (d) and Annex IV

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Foreword

I am thrilled to unveil our very first Environmental Statement, following successful registration on 17 January 2025 under the prestigious EMAS management standard for our environmental management system.

I strongly believe that both we, as individuals, and our organisations have a duty to protect the environment. We should all strive to lighten our footprint on the earth where we can; we know we can always do more, and that every little act can make a big difference. For me, this is a personal, as well as professional, responsibility.

Since the introduction of the Green Deal in 2019 and the European Climate Law in 2021, we have witnessed transformative changes at both the EU and national levels. These legislative advancements have driven structural shifts and inspired changes within organizations and individuals alike.

As a dedicated body of the European Union (EU), the EMA embraces its vital role in protecting our environment for both current and future generations. Our mission is to champion scientific excellence in the evaluation and supervision of medicines, ensuring the health and well-being of both the public and animals across the EU. In doing so, we are committed to exceeding the expectations of our stakeholders by preventing pollution, promoting sustainable resource use, and minimizing waste and emissions.

Our commitment to environmental stewardship is reflected in our operations from an environmentally certified building that boasts a BREEAM Excellent rating and an Energy Label A++. We are dedicated to continuous improvement, striving to further reduce our environmental footprint.

In 2024, we reaffirmed our vision to be a climate-friendly and resource-efficient organization by revisiting our Environmental Policy. With this renewed commitment, the Agency’s leadership is poised to provide strategic direction and foster ongoing enhancements in environmental management at every level. I look forward to seeing more progress in the year ahead.

Emer Cooke
Executive Director

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1. Introduction to this document

This environmental statement has been developed to provide information to the public and other interested parties about the European Medicines Agency's (the 'Agency') environmental performance and initiatives in 2023. It is prepared in accordance with the European Eco Management and Audit Scheme (EMAS) standard, revised Regulation (EC) No 1221/2009 included Annexes I, II, III as amended in 2017 to reflect the revised ISO 14001:2015, and Annex IV, as amended in 2018 to reflect the environmental reporting requirements, whereby it also fulfils the requirement of disclosure of information relating to environmental matters in accordance with Directive 2014/95 (EU)[1]. Furthermore, the Agency is voluntary using the JRC Science for Policy Report 'Best Environmental Management Practice for the Public Administration Sector' [2](BEMP) for the preparation of this Environmental Statement, specifically chapter 2 and 12, since that is the Management Practice closest to our activities. Additionally, the Agency is also voluntarily using the European Commission Decision (EU) 2019/61 on the sectoral reference document on best environmental management practices, sector environmental performance indicators and benchmarks of excellence for the public administration sector[3] under the EMAS regulation (SRD), with special focus on chapter 3.1, Best Environmental Management Practices for sustainable offices and chapter 3.11 Best environmental management practices for green public procurement taken into account, when applicable, for the same reasons.

The Agency uses an environmental management system (EMS), which is registered under the EMAS regulation, in January 2025.

This environmental statement is validated by a licensed environmental verifier through a public procurement procedure, to be compliant with the EMA's pending registration under EMAS. It was made public by uploading it onto the EMA website, for the public and other interested parties to access. The Agency will publish environmental statements on an annual basis, made available for download on its website. This statement applies to all staff members, delegates, contractors, visitors and other authorised persons working within the premises of the Agency without exception.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0095
[2] https://susproc.jrc.ec.europa.eu/product-bureau/sites/default/files/inline-files/PublicAdminBEMP.pdf
[3] Commission Decision (EU) 2019/61 of 19 December 2018 on the sectoral reference document on best environmental management practices, sector environmental performance indicators and benchmarks of excellence for the public administration sector under Regulation (EC) No 1221/2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)Text with EEA relevance. (europa.eu)

2. EMAS validation of this document

ENVIRONMENTAL VERIFIER'S DECLARATION ON VERIFICATION AND VALIDATION ACTIVITIES

Dr. Georg Sulzer with EMAS environmental verifier registration number DE-V-0041, accredited or licensed for the scope 99 Activities of extraterritorial organisations and bodies (NACE Code) declares to have verified whether the site as indicated in the environmental statement of the organisation

European Medicines Agency (EMA)
Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands

meet all requirements of Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS) amended by Commission Regulation (EU) 2017/1505 of 28 August 2017 and by Commission Regulation (EU) 2018/2026 of 19 December 2018.

By signing this declaration, I declare that:

— the verification and validation has been carried out in full compliance with the requirements of Regulation (EC) No 1221/2009 amended by Commission Regulation (EU) 2017/1505 of 28 August 2017 and by Commission Regulation (EU) 2018/2026 of 19 December 2018.

— the outcome of the verification and validation confirms that there is no evidence of non-compliance with applicable legal requirements relating to the environment,

— the data and information of the environmental statement of the organisation ECHA reflect a reliable, credible and correct image of all the sites activities, within the scope mentioned in the environmental statement.

This document is not equivalent to EMAS registration. EMAS registration can only be granted by a Competent Body under Regulation (EC) No 1221/2009. This document shall not be used as a stand-alone piece of public communication.

Done at Altfraunhofen on December 16th, 2024.

Dr. Georg Sulzer
Hangleite 2, D-84169 Altfraunhofen, Germany

EMA will provide and publish another actualised environmental statement in October 2025 and in October 2026. We will provide and publish the next consolidated environmental statement in October 2027.

3. About the European Medicines Agency

3.1. European Medicines Agency

The EMA is a decentralised body of the European Union (EU), based in Amsterdam, the Netherlands. The Agency was established in 1995 and operates under Council Regulation No 726/2004 to provide a system for the authorisation of medicinal products for human and veterinary use.

Under the 'Pharmaceutical Strategy for Europe' adopted on 25 November 2020 EMA will contribute to creating a future proof regulatory framework with actions to ensuring access to affordable medicines for patients and addressing unmet medical needs, supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry and the development of high quality, safe, effective and greener medicines, enhancing crisis preparedness and response mechanisms, diversified and secure supply chains, address medicines shortages and ensuring a strong EU voice in the world, by promoting a high level of quality, efficacy and safety standards.

On the level of EMA and the network of national competent authorities of the 27 EU Member States plus those of Iceland, Liechtenstein and Norway the direction is further developed to support change and prepare the network to play their part and implement the needed actions. The high-level goals and supporting recommendations will feed into each members detailed workplans whilst acknowledging its broad guiding principles of supporting environmental sustainability through reduced use of resources, emissions, degradation and pollution related to pharmaceuticals.

Additional direction is provided by the European Green Deal and other EU Priorities with an aim to improve public and animal health and the environment with a number of measures.

3.2. Description of Activities and Services

The Agency's main responsibility is the scientific evaluation of medicines for human and veterinary use and the expert meetings linked with these activities, all carried out in a general office environment supported by back-office services such as meeting administration, IT, catering, housekeeping, security, facility maintenance and reprographics. Our mission is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the EU.

The Agency facilitates development and access to medicines, evaluates applications for marketing authorisation, monitors the safety of medicines across their lifecycle and provides information to healthcare professionals and patients.

To establish the classification of the Agency activities the Nomenclature des Activités Économiques dans la Communauté Européenne (NACE) is used. The one applicable to the EMA is the following:

99.00 - Extra-territorial organisations and bodies.

3.3. The EMA Environmental Roadmap

The Agency developed its first Environmental Strategy in December 2013 which was replaced with the Environmental Management Roadmap 2020 to 2024, approved by the EMA Executive Board (EXB) on 14 January 2021. The roadmap sets out the EMA commitment to develop and implement the existing environmental management system, EMS, in line with the requirements of ISO 14001:2015 and to register with EMAS before the end of 2024, with focus on: monitoring and calculating emissions of greenhouse gas from direct and indirect activities, maintaining an environmentally friendly approach to the occupancy of the EMA building, providing an environmentally friendly working environment to staff including delegates and visitors, maintaining a green approach in procurement, include environmental

targets and reporting in its planning and reporting, promote staff awareness and involvement and preparing for possible carbon off-setting.

The roadmap further set up the steps toward EMAS registration by performing an external review of the prepared EMS, by completing an internal audit of the EMA environmental management system, implementing any improvement actions as a result of the audit, and sourcing of an EMAS verifier for the final assessment.

4. European Medicines Agency Environmental Management System (EMA EMS)

4.1. About EMAS

The EU Eco-Management and Audit Scheme (EMAS) was established by the European Commission to assist organisations in evaluating, reporting and ultimately improving environmental performance. EMAS is fully compatible with, and largely based upon, the ISO 14001 Environmental Management System (EMS), but has additional requirements including conducting an initial environmental review, reporting on a set of core indicators and the publication of the environmental statement.

The EMA established its EMS in 2021 and achieved EMAS registration on 17 January 2025. This is the first environmental statement produced by the EMA in full accordance with the EMAS regulation.

4.2. Context and purpose of the EMA EMS

The implementation of an EMS at EMA intends to clarify the direct environmental aspects and impacts from the Agency's activities, to be used to support an approach of continuous improvements through the principles of plan, do, check, act cycle. Through the structure of EMAS a systematic review process is reinforced that can be used to determine suitable objectives, targets and actions and can also support identifying opportunities to broaden the scope of the EMS to include the indirect aspects of the EMA core activities, where relevant.

The EMA EMS is registered under the EU Eco-Management Audit Scheme – Regulation (EC) No 1221/2009 (EMAS), Commission Regulation (EU) 2017/1505 (updated Annexes I, II and III) and Commission Regulation (EU) 2018/2026 (updated Annex IV).

4.3. Scope of the EMA's environmental management system

To determine the scope of the EMA EMS the EMA's structure, compliance obligations, the needs and expectations of relevant stakeholders and the level of control and influence of activities resulting in actual or potential environmental risks and impacts. The Agency operates from its headquarters premises in Amsterdam, the EMA building. Due to the environmental impact from staff and delegate

business travel those emissions are also included within the scope of the EMA EMS. External services provided by procured services that operate from a physical structure i.e. external archive services is not included in the scope of the EMS due to the services being provided in shared facilities and due to the very limited ability for the Agency to be in control of those premises. It is procured with implementation of green criteria, in line with Public Procurement procedures.

4.4. Methodological assumptions

For calculation of the Agency carbon footprint the Greenhouse Gas Protocol methodology Scope 1, 2 and 3 is applied.

For calculation purposes the number of full time employees (FTE) per year from the EMA Annual Activity Reports have been used.

For monitoring consumption data the information provided as supporting information to invoicing by the various contractors providing the services, as well as the EMA building BMS system have been used.

4.5. The EMA premises

The Agency operates its activities from the offices at Domenico Scarlattilaan 6 (the EMA building) in Amsterdam. The office space is leased from Rijksvastgoedbedrijf, the Dutch Central Government Real Estate Agency (CGREA), and consequently the Agency are bound by the terms of a rental lease. The EMA building is built on lot AK5224 in Amsterdam Zuid with a land area of 4,850 Sqm for the sole use of the Agency.

The Agency is the single occupier of the EMA building with a net lettable area, NLA, of 33,411 m^2 with three floors dedicated to meeting-rooms and conference facilities, two technical floors with an NLA of 944 Sqm and offices spread over 16 floors providing work-stations for a daily occupation capacity of 1,300 people. The EMA building is a newly developed energy efficient building with an Energy Label A++ and a BREEAM 'Excellent' rating. The structure of the building is a concrete core, steel piles and frame and pre-fabricated concrete floor-slabs. Fitting-out elements are made of low VOC materials and energy and water efficient fixtures. The building also includes two floors with bicycle parking with a total of 705 racks. Car parking with 104 spaces is located outside of the rented space in two existing garages. The EMA building design includes offsetting of the carbon footprint with installation of solar panels in a green field location, energy recovery lifts, an internal green wall and access to a roof garden on the third-floor roof-terrace with plants and an insects-hotel. The roof terrace of 780 Sqm has a water retention system whereby rainwater can be stored to be used for watering of the plants. In addition, efficient heating, ventilating, and air conditioning systems (HVAC) and water systems were installed to ensure the healthiest and most comfortable work-space conceivable as well as biodiversity enhancer.

The following areas of resource consumption are included within the scope of EMAS:

- Fugitive emissions from air-conditioning
- Electricity consumption
- District heating and cooling
- Water consumption
- Waste generation: glass, plastic, paper, metal, food, non-recyclable
- Business travel

- Printing, i.e. paper consumption

Furthermore, the building is served with excellent transport links, most notably the Tram, the Metro, National Rail, several buses as well as being close to the A2 and A10 for access by car and taxi, providing an efficient commute for all personnel and visitors.

The landlord, CGREA, is a partner of the Dutch Green Building Council.

4.6. Staff and delegate mobility

EMA has a set of rules for staff and delegate duty travelling:

- Internal Guidance on the new guide to missions and authorized travel

- Rules for reimbursement of delegates and experts

During 2023 the interim approach to staff missions remained in place, as approved by EXB in 2022 to support virtual participation when possible and limit the amount of EMA staff participating at the same meeting/event. In parallel the decision to perform every other scientific committee meeting virtually also remained implemented. The mobility of staff and delegates for business travel is currently part of the scope of the EMS. In 2024 staff commuting will become part of the EMS as broadening of the scope. In mid-2023 a first draft of the new mission rules were received from the European Commission (EC) and are currently being reviewed, aimed for implementation in 2025.

4.7. Governance

The Agency has a Management Board, an Executive Director, seven Advisory Functions, three Task Forces and five Divisions with 15 subordinated Departments. The Executive Director since 15 November 2020 is Ms Emer Cooke.

The Management Board meets four times a year and is made up of the Executive Director and representatives from the EU27, plus representatives from the European Parliament, the European Commission, organisations relevant to the work of the Agency and observers from the European Economic Area (EEA).

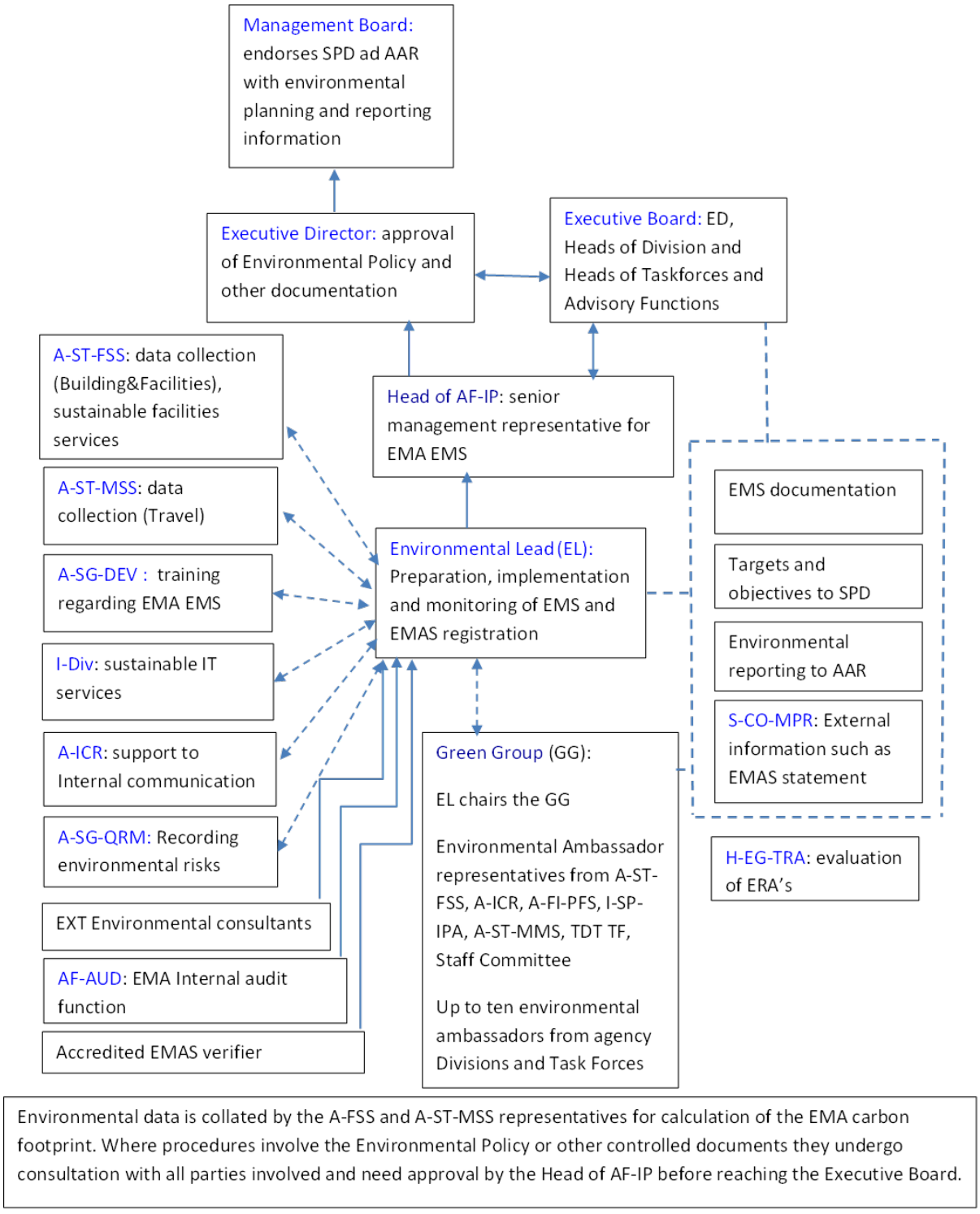
Ultimate responsibility for environmental management sits with the Executive Director. The Executive Director and senior management forms the Executive Board (EXB) of EMA. The Head of the Advisory Function Institutional and Policy, Ms Hilde Boone is the senior management representative for Environmental Management at EMA, who reports directly to the Executive Director.

The coordination of the EMA EMS is managed by the EMA Environmental Lead, under supervision of the Head of Institutional and Policy and is performed in a matrix structure. The Environmental Lead is the chair of the EMA Green Group for staff involvement and awareness. The Green Group is formed of six functional representatives identified as having a key responsibility towards embedding a sustainable approach in their ordinary tasks, one representative from the Agency Staff Committee and up to ten voluntary representatives from other parts of the Agency, all being identified as Environmental Ambassadors. The Green Group is focusing its activities on the organisational aspects and how staff and visitors behave in the EMA building and in the performance of their ordinary tasks as well as raising general environmental awareness to improve and reduce the environmental impact from the Agency’s activities.

The Green Group meets as a minimum twice a year and may also set up ad hoc subcommittees for arranging specific activities or event. This is outlined in the Green Group mandate (‘EMA Green Group mandate’), revision 2, dated 6th September 2024.

The organigram below illustrates the governance structure of environmental management at EMA and the resources involved.

Figure 1. EMA environmental management system, matrix structure



5. EMA Environmental Policy

The EMA Environmental Policy was last updated with the effective date 15 May 2024, with review date on 15 May 2027. The Policy has been made public on the EMA website. The updated version supersedes the previous version, effective 14 January 2021.

Introduction and purpose

As an European Union (EU) body the European Medicines Agency (EMA) acknowledges its institutional responsibility to safeguard the environment for present and future generations.

Recognising that social and civil responsibilities of the Agency's activities have the potential to affect the environment, the Agency considers that a long-term sustainable approach and proactive environmental management generates environmental, social and economic value for the community in which we operate. EMA strives to meet and exceed the expectations of our stakeholders for the prevention of pollution, the sustainable use of resources and the minimisation of waste and emissions.

Scope

This environmental policy covers the Agency's operations and staff, also when on missions and travelling to and from work. The policy also applies to other persons such as interims, trainees, seconded national experts, delegates, contractors and visitors working within the premises of the Agency without exception.

Policy statement

Improving Environmental Performance

EMA's vision is to be a climate friendly and resource efficient organisation and in that context in order to fulfil these commitments, the Agency's leadership will provide strategic direction and promote the continual improvement of environmental management at every level.

The Agency is committed to:

• Ensure compliance with local, national and EU environmental legislation, as well as regulatory and voluntary obligations within the remits of existing regulations;

• Maintain an open dialogue to promote and share environmental knowledge and best practice with all stakeholders, including but not limited to other EU Institutions and EU Agencies through the Groupe Interinstitutionnel de Management Environnemental (GIME) network and the Greening Network of the EU Agency Network; • Maintain staff's awareness and understanding of environmental issues by setting up a network of staff environmental ambassadors, organised as the Green Group, to promote good environmental practices throughout the Agency;

• Ensure EMA staff, contractors and delegates at all levels are aware of their environmental responsibilities and empower them to participate in efforts to improve the Agency's environmental performance;

• Set targets and objectives for continuous improvements, implement measures to achieve these and put in place systems to monitor their progress;

• Encourage suppliers by application of voluntary EU Green Public Procurement Criteria and Requirements in the Agency's procurement procedures;

• Prepare for implementation of a carbon removal regime of the environmental impact in line with other EU Agency's and Institutions under existing and future regulations.

In order to support minimisation of our environmental impacts and continually improve our performance towards carbon neutrality EMA has a target to register to the European Eco-Management and Audit Scheme (EMAS) and to each year publish a statement of its environmental performance.

Changes since last revision

The policy was updated with minor language improvements and to reflect the outcome of the Agency's Internal Environmental Audit performed in 2023 which confirmed compliance of the policy with EMAS requirements, as well as developments applicable to EU agencies and institutions in pursuit of registration to EMAS.

6. Environmental Aspects and Impacts

To understand the EMA environmental performance and following the systematic review of all environmental aspects and the corresponding environmental impacts linked to our business activities undertaken in 2021, preparations for an internal environmental audit with fine-tuning of the environmental management system documentation have been in focus during 2023. Environmental aspects concern an element of an organisation's activities, products or services that have or can have an impact on the environment causing a change to the environment, whether adverse or beneficial, wholly or partially resulting from an organisation's activities, products or services. The internal environmental audit was performed in December 2023 with the audit report received in January 2024 confirming the EMA EMS readiness to pursue the next step towards EMAS registration.

The review also considered whether the aspects identified were under "direct" or "indirect" control of EMA. Direct aspects concern business activities where EMA have the ability to control the activity, whereas indirect aspects are those that are managed by third parties but where the activities by EMA may still influence the activity. The environmental aspects identified by this review provide the basis of the EMA EMS with an aim to reduce our environmental impacts through the ongoing performance management of these aspects.

The agency has evaluated the environmental aspects and impacts whilst activities are performed under normal operations as well as in emergency situations. To prepare for emergency situations the Agency performs full building evacuation practices and have allocated floor marshals on each floor to support an orderly evacuation of the premises. In 2023 the Agency did not experience any real emergency situations.

By evaluating all environmental aspects against pre-defined criteria as specified with the EU Eco-Management Audit Scheme – Regulation (EC) No 1221/2009 (EMAS) and Commission Regulation (EU) 2017/1505 (amending Annexes I, II and III), and Commission Regulation (EU) 2018/2026 (amending Annex IV) a risk-based assessment of the probability, severity and frequency of impact can be performed, and the EMA's ability to influence and control these impacts.

The Agency recognises the amendment of ISO 14001 regarding Climate Change. Based on the Agency's activities and location it is currently not determined as a relevant issue subject to specific actions or controls.

Any environmental aspects that are already subject to existing environmental legislation and any aspects deemed to be significant will be prioritised based on expected probability, severity, frequency of impact and the EMA's ability to influence and control them.

Table 1. The environmental aspects arising from the EMA activities

Significance	Environmental aspect	Environmental impact	Normal Conditions	Emergency conditions
Potential high significance	Air emissions	Air pollution Greenhouse gas effect	Business travel staff and delegates Diesel power emergency generator Cooling agent for A/C system	An emergency related to access to network electricity and operating the building by using the diesel generator will increase emissions to air. For emergencies that will require the Agency to operate in a fully virtual mode the emissions from business travel will be significantly reduced.
	Energy and fuel use	Depletion of natural resources Greenhouse gas effect	Business travel staff and delegates Heating, cooling and ventilation Lighting IT and AV equipment Catering equipment	Most emergency situations will not increase the emissions from energy and fuel but may temporarily peak if emergency travel is needed. In the longer term the emissions will instead significantly reduce. If an emergency leads to the diesel generator being required as the main source of power, emissions from fuel use will increase.
Low to medium significance	Water use	Depletion of natural resources	Building installations Toilets Showers Catering Cleaning Drinking water	Most emergency conditions will not change the impact on the environment from water use since a majority of the use come from building installations. Mitigating measures to limit water use are implemented in the design of the building

				and installations rather than in the operations. Even a vacated building would maintain some installations in operation even though some reductions would be expected due to reduced use.
	Paper use	Depletion of natural resources	Printing Communication Office use	The Agency have fully digital work-flows and rely on paper use to a low level. This would not be affected in emergency conditions since printing would not be possible unless the digital platform works.
	Waste production	Air, water and ground pollution	Catering Cleaning Office consumables IT and AV equipment Building maintenance	Under emergency conditions affecting the cooling or freezers there may be a peak of food waste that will become unsuitable for consumption. Other waste production may reduce significance due to emergencies.
	Biodiversity	Ground pollution	Lot of EMA building 4850 Sqm Nature oriented area of 780 Sqm roof terrace with a water-retention system and insect-hotel	For an emergency involving a leak from the diesel generator or fire there may be an increased significance of ground pollution. Mitigating measures are implemented in the building to reduce the impact.
	Noise	Noise pollution	Diesel power emergency generator Deliveries and collections	If an emergency leads to the diesel generator being required as the main source of power, noise pollution will increase. Mitigating factors include the

				enclosure of the generator, the Agency location next to the A10 motorway and the train and metro-lines, and the absence of residential buildings in the near vicinity.
Indirect impact from third party, as a result from EMA core activities	Discharges from third party activities	Air, water and ground pollution	Manufacturing Use Disposal	An emergency condition at the Agency or one that affects the Agency's staff and delegates to be present at the EMA building will not have an impact on the third-party activities.

7. Objectives, Targets and Environmental Performance of the European Medicines Agency

This section outlines the Agency's environmental objectives and targets identified in the Annex VI to the Agency's Single Programming Document prepared on an annual basis relating to the Agency's environmental aspects and impacts.

7.1. Objectives, Targets and Actions

To improve the EMA environmental performance the following objectives are identified, supported by targets. To realise the stated objectives and targets a number of actions have been planned to address the aspects and impacts identified. These will be further developed over time as needed and complemented by a defined implementation-plan and communication strategy.

Table 2. EMA objectives, targets and actions

Aspect	Environmental objectives	Key Performance Indicator	Target 2025 - 2028	Actions to achieve environmental objectives
Direct	Energy efficiency: "EMA drives energy efficiency in line with good practices"	Total annual consumption of energy (heating, cooling, electricity) per FTE;	To establish a reduction trend over the programming period.	Investment in upgrading the building management system, allowing for adjustments of temperature set-point to optimise efficiency.
		Total share of energy from sustainable sources.	Continue to use 100% renewable electricity	Replacement scheme of electronic equipment such as laptops[4] and other small electrical

[4] IT hardware procurements are concluded under DiGIT-run FWCs accessible to all participating EUI's. These FWCs include the requirement that all tenderers comply with the applicable obligations under environmental, social and labour law established by Union law, national law and collective agreements or by the international environmental, social and labour law provisions.

				devices, products and appliances for further energy efficiency[5], when technically and financially justifiable
	Material efficiency: "EMA drives material efficiency in line with good practices"	Consumption of sheets of office paper per FTE) per working day	Monitor consumption	Promote reduced use of single-use materials along "circularity approach" Promote paper-less work-flows and digitisation
	Material sustainability: "EMA implements green criteria in its procurements for conscious selection of sustainable materials"	Choice of materials used for the environmental impact and reduction of hazards	Green criteria to be used in all procurements where applicable	Promote choice of sustainable materials with eco-labels or equivalent products and sustainable/fair-trade and seasonal produce.
	Water – not relevant due to the water efficiency at the EMA building	Total annual consumption of water per FTE	Monitor consumption	
	Waste: "EMA drives waste reduction in line with good practices"	Total annual generation of waste per FTE	To monitor all waste streams generation.	Monitor total waste per FTE and year, monitor WEEE waste generation and disposal by volume, and manage waste along a "circularity approach"
	Biodiversity – not relevant due to no further land being taken into use	N/A	N/A	N/A
	Emissions: "EMA drives emission reduction, including carbon zero by 2050"	Emissions of greenhouse gases [t] through office occupancy; Emissions from meetings with external participants reimbursed by the Agency; Emissions from staff duty travel; and	Target to reduce emissions from delegates travel with 40% compared with 2015, i.e. carbon budget of 1600 TCO2e. Long term target to reduce with 50% by 2030, i.e. carbon budget of 1335 TCO2e; Target of 5% annual reduction of emissions from staff travel, during the programming period Emissions from staff commuting and teleworking will be	Monitor and report travel by staff and delegates towards the agreed targets on a regular basis, with consideration and for alignment to rules in place, for a balanced approach between face-to-face and virtual participation in meetings and other events. Staff survey regarding commuting and teleworking on an

[5] When selecting Hardware to add to the Catalogues (for example under MEQ IV Lot 1) the energy rating of the devices (for laptops, desktops & monitors) is one of the criteria used to evaluate the various devices proposed by the tenderers for inclusion in the relevant catalogues.

		Emissions from staff commuting and teleworking	monitored over the programming period	annual basis for data gathering. Awareness campaigns about emissions from different means of commuting and from different energy solutions.
Indirect	Environmental effects of medicines for human and veterinary use (ERA)	As included in the single programming document (SPD) 2025-2028		Actions as included in the SPD 2025-2028

Table 3. Other objectives and targets of an organisational or process-related nature

	Objective	**Target**
	Include an option for offsetting the generation of carbon emissions with carbon reduction measures in the highest impacting goods and services subject to public procurement	Identify tender procedures suitable for including an option for carbon removal certificates or similar carbon reduction measures and seek support from the helpdesk for green criteria to develop them
	Regularly perform internal environmental audits of the EMA EMS	Perform internal environmental audits on part of the EMA EMS on an annual basis, and a full Internal Environmental Audit and validation audit every three years

The Agency has an ambition for alignment with the European Climate Law target of reducing net carbon greenhouse gas emissions by at least 55% by 2030 and to reach climate neutrality by 2050.

7.2. Completed Actions

Table 4. Actions supporting other objectives and targets

Action	**Due**	**Status**
Providing an update to the EMA EXB of the EMA Environmental Management activities and the actions needed towards registration to the EMAS Management Standard System	2023	Completed
Prepare information of the selected tool (United Nations Climate Change UNFCCC) to measure ones individual carbon footprint, to be used in induction training to new staff	2023	Completed
Replace the EMA Internal Guidance for Green Public Procurement to the EC Public Procurement	2023	Completed

Management Tool for implementation of green criteria in the Agency's public procurements		
Perform Internal Environmental Audit of the EMA EMS	2023	Initiated December 2023 and completed January 2024
Participate in inter-institutional procurement procedure for Certification to Management Standard Services validate the EMA EMS to the EMAS regulation and register to EMAS	2023	Procedure completed in 2023 with contract coming into place January 2024
Reduce the total number of MFD printers of the office floors and replace the printer fleet with equipment with energy efficient labels such as EPEAT and Energy Star	2023	Completed
Removal of all single-use items such as paper cups and take-away boxes from the EMA catering facilities	2023	Completed
Introduce option for offsetting or carbon removal in the procurement procedures of goods and services	On-going	Completed for 2023 and planned for 2024

7.3. Planned Actions

Table 5. Planned future actions supporting the EMA EMS objectives and targets

Action	Due	Status
Performing a Survey to capture carbon emissions from staff commuting and home-workstations	2024	Completed
Provide training to staff during the EMA Development Day regarding: Decoding carbon footprint at the office and at home	2024	Completed
Green Group Campaign: Switching off laptops and screens during the night and at weekends	2024	Planned
Increase the sustainable food offers in the EMA catering facility	2024	Implemented
Replace paper business-cards with digital business-cards	2024	Implemented
Prepare Environmental Management Roadmap 2025 to 2028: EMA fit for 55	2025	Planned
Liaising with businesses and organisations in the Green Business Club Zuidas through sustainability projects, for example: clothes collection for upcycling and re-use, lobbying towards increased	2025-2027	Planned

share of sustainable fuels in the Amsterdam Zuidas district heating system		
Energy Efficiency improvements, for example: review cooling of in-house MER and SER for potential energy efficiency measures to be introduced	2025-2027	Planned

8. Environmental Performance indicators

8.1. Gross consumption

EMA implements its environmental management in accordance with the principles of plan, do, check, act cycle for the offices at the EMA building.

Energy

Energy consumption data is collected on a monthly basis from the Building Management System (BMS) and from the monthly invoicing.

To support business activities at the EMA building two main sources of energy are used:

- **Purchased electricity** provides the requisite power for lighting, IT and AV equipment, operation of lifts, ventilation, A/C and other electrical equipment. The electricity grid provider at the EMA building is Liander and the electricity is Eneco providing 100% renewable energy from wind-mills and solar panels. The CO^2-emissions from the grid loss is 0,0375 kg per kWh[6].

- **Heating and cooling** is provided through the Amsterdam district heating and cooling system under the operator Vattenfall. In 2023, heating in Amsterdam Zuid was produced with 90% from an electrical plant (gas), 5% gas-fired, 2% waste incineration and 3% gas-engines, recognising as a total 3% to be from renewable resources and 20% from residual heat. The CO^2-emissions per GJ is 24.4kg for the district heating[7] and 11.7kg CO^2 per GJ for district cooling. Cooling recognises 85% to be from renewable resources.

The data are monitored and compared year on year and as reference for benchmark of excellence the EMA building is compared with energy-efficiency for newbuilds, with buildings to be designed with a total primary use lower than 60 kWh/Sqm/year, and with the criteria for Passive Houses of non-residential buildings by the PassivHaus Institut indicating a total specific energy demand of equal or below 120 kWh/Sqm and year.

Water

Consumption data of the water used at the EMA premises are received on a monthly basis from the water provider in Amsterdam and the region, Waternet. The data is monitored and analysed year on year and compared with the benchmark of excellence, see chapter 8.3.

[6] The emission factor used for grid-losses is assessed as the average from wind-power and solar panel (14g/kWh and 61g/kWh/2=37,5g/kWh)

[7] Source : https://www.vattenfall.nl/stadsverwarming/warmte-etiket/

Waste

To support, manage and minimise production of waste the Agency has implemented an advanced waste management system. For prevention of the generation of waste the Agency procedures and archives are paperless. The Agency has since many years implemented green criteria in its public procurements to ensure the purchase of durable equipment and consumables, environmentally friendly products for cleaning services and encourage staff and visitors to use reusable cups for water and refreshments instead of single-use items.

To support segregation of waste the Agency provide waste separation bins throughout the EMA building in line with requirements of the City of Amsterdam.

Data of the quantities of waste generated is provided on a monthly basis by the waste removal contractor and used to monitor the collected fractions. The waste collector supports circular waste management with a target of pre zero waste to landfill and sees waste not as waste but as raw material for new products. For monitoring of waste production towards benchmark of excellence see chapter 8.3.

Minimising consumption of office paper and consumables

As an EU Agency with mainly office work the main **materials** used are printing paper. The EMA purchases EU Eco-Label printing paper and have follow-me-print activated throughout the EMA building pre-set for double-sided printing in black and white with no provision of desk-top printers. A vast majority of all work-flows are digitalised including the use of digital signatures. For monitoring of office paper consumption towards benchmark of excellence see chapter 8.3.

Minimising the environmental impact of commuting and business travel

Information regarding real time public transport is provided on digital screens next to the entrance visible when leaving the Agency. The EMA building provides 705 spaces of bicycle parking divided between two floors including twenty-seven charging-points for e-bikes, to be compared with 104 car-parking spaces located outside of the EMA building.

For business travel by staff 'Guide to missions and authorised travel' provide guiding principles and encourages participation as far as possible by the use other communication methods such as videoconferencing. During 2023 the level of business travel increased due to the lifted Covid-19 pandemic restrictions and a subdued need for some face-to-face interactions.

All staff are equipped with laptops with built-in camera for video-conferencing and software for secure access.

During 2023 staff have been able to maintain remote working with up to 60% of the working time. Until April 2024 teleworking from abroad was allowed with up to one week per month. As of May 2024 staff are allowed ten days of teleworking from abroad per year.

Minimising the environmental impact of canteens and coffee bars

The procured catering services introduced sustainable requirements such as seasonal, organic food and ensuring vegetarian/vegan options on a daily basis. The EMA Green Group and the Facility Service's catering contract manager regularly promotes campaigns for sustainable food choices and vegetarian theme days throughout the year. The weekly menu is presented on the EMA intranet with symbols providing information of locally-sourced produce and vegetarian/vegan dishes. Any food waste generated during preparation or by disposal (23% of total waste) is sent for anaerobic digestion. By

mid-2023 all single use plastic/paper cups and containers for take-out items were removed from the EMA restaurant.

Minimising the environmental impact of the organisation of meetings and events

During 2023 the interim approach to scientific committee meetings was maintained with a combination of face-to-face meetings and virtual meetings. In total there is a significant increase in travel due to the long period of only virtual meetings, however this is expected to reduce over time with the approach to hold every other meeting in a virtual setting and encourage sustainable travel where feasible.

Catering facilities for incoming delegates and visitors are provided with reusable cups and glasses. All meeting-rooms are equipped with large screens and meeting documents are provided in digital format only. Name-plates for the delegates are printed on high quality, sustainable paper and re-used for the return visitors i.e. the delegates. Hotels in the near vicinity to the Agency are recommended and visitors are provided with information how to reach the Agency by public transport.

Gross consumption

The gross consumption of the monitored aspects is shown in table 6.

Table 6. European Medicines Agency's Environmental Performance Indicators, gross consumption

Indicator	Consumption	2021	2022	2023	BEMP
Energy	Total energy (MWh)	3.157	3.572	4.175[1)]	
	- electricity	1.736,2	2.144,9	2.228,2[1)]	
	- district heating	1.263,6	1.218,6	1.105,1[1)]	
	- district cooling	157,6	208,8	842[1)]	
	Renewable energy (MWh)	1.950,7	2.365,2	2.977	
	- electricity	1.736,2	2.144,9	2.228,2	
	- district heating	75,8	36,6	22,2	
	- district cooling	138,7	183,7	715,7	
	Share of energy from renewable source (%)	62%	66%	71%	
	- electricity	100%	100%	100%	100%
	- district heating	6%	3%	3%	100%
	- district cooling	88%	88%	85%	
	Energy produced on site	0	0	0	

Materials	Printing paper (no of A4 sheets)	613.747	554.486	672.426	EU ECO-label
Water[1)]	Annual water use (m^3)	3.660	5.958	7.566	
Waste	Total waste (kg)	41.998	54.717	64.267	
	Paper (kg)	5.070	5.476	6.164	
	Plastic (kg)	763	451	1.199	
	Glass (kg)	1.257	3.204	3.922	
	Food (kg)	13.848	13.691	14.756	
	Confidential (kg)	1.719	1.998	2.050	
	Non-recyclable (kg)	19.341	29.907	36.176	
Biodiversity	Built-up area (Sqm)	4.850	4.850	4.850	
	Nature oriented area on site, roof terrace garden (Sqm)	780	780	780	
Emissions to air	Emissions from building (TCO^2)	218,5	253,41	277	
Emissions to air	Total (TCO^2) from travel	0,8	791,65	1.682,9	
	- Delegates travel	0,8	664,26	1.422,8	
	- Staff missions	0	127,39	260,1	

Total Emissions	Emissions of CO_2, CH_4, N_2O, HFCs, PFCs, NF_3 and SF_6, expressed in tonnes of CO_2 equivalent	219,3	1.045,1	1.959,9	

1) Data for electricity, heating and cooling for 2023 and data for water consumption for all years are based on information extracted from the EMA building's Building Management System

To further analyse and monitor the gross consumption the total annual amounts per Full Time Employee (FTE) and the total annual amount per square meter (Sqm) is calculated using the information of FTE from the EMA Annual Activity Report, and since 2020 the square-meters for the EMA building. Further detail is presented in the below, table 5.

Table 7. Average FTE and size of the premises during 2019 to 2021

	2021	2022	2023
Number of FTE*	888	915	927
Office space (m^2)	33.411	33.411	33.411

** Number of FTE resources as reported in the EMA Annual Activity Report's, Annex 5*

8.2. Consumption per Sqm of occupied office space

The gross consumption is evaluated against the EMA headquarters as environmental performance indicator of the efficiency of the EMA building.

The environmental performance indicator for building related data is presented below with consumption per square meter and year. For reference to best practice, a limited number of benchmarks of excellence are available. Monitoring is therefore focussed on year by year comparison from the approach of plan, do, check, act cycle.

Table 8. European Medicines Agency's Environmental Performance Indicators, per Sqm offices

Indicator	Consumption	2021	2022	2023	BEMP
Energy	Total energy (kWh/Sqm)	94,5	106,9	125	
	- electricity	52	64,2	66,7	
	- district heating	37,8	36,5	33,1	
	- district cooling	4,7	6,2	25,2	
	Renewable energy (kWh/Sqm/y)	58,4	70,8	89,1	
	- electricity	52	64,2	66,7	
	- district heating	2,27	1,1	1	
	- district cooling	4,15	5,5	21,4	
	Energy produced on site	0	0	0	

Materials	Printing paper (n A4 sheets)	N/A	N/A	N/A	
Water	Annual water use (m^3/Sqm)	0,11	0,18	0,23	0,25
Waste	Total waste (kg/Sqm)	N/A	N/A	N/A	
	Paper (kg)	N/A	N/A	N/A	
	Plastic (kg)	N/A	N/A	N/A	
	Glass (kg)	N/A	N/A	N/A	
	Food (kg)	N/A	N/A	N/A	
	Confidential (kg)	N/A	N/A	N/A	
	Non-recyclable (kg)	N/A	N/A	N/A	
Biodiversity	Built-up area (Sqm lettable area/Sqm land)	6,89	6,89	6,89	
	Nature oriented area on site, roof terrace garden (Sqm nature are/Sqm built-up area)	0,16	0,16	0,16	
Emissions to air	Emissions from building, KCO^2/Sqm	6,54	7,58	8,29	
Emissions to air	Total (TCO^2) from travel - Delegates travel - Staff missions	N/A	N/A	N/A	
Total Emissions	Emissions of CO_2, CH_4, N_2O, HFCs, PFCs, NF_3 and SF_6,	6,56	31,3	58,7	

	expressed in tonnes of CO_2 equivalent (KCO^2/Sqm)				

8.3. Consumption per average FTE

For further presentation of the EMA environmental performance the gross consumption is evaluated against the average number of full time equivalents employed at the Agency. Due to new starters and leavers taking place over the course of the year and the allocation of resources approved under the budget may fluctuate this reference is presented on an annual basis.

Table 9. European Medicines Agency's Environmental Performance Indicators, per FTE

Indicator	Consumption	2021	2022	2023	BEMP
Energy	Total energy (kWh/FTE)	3.555,7	4.082,6	4.504,1	
	- electricity	1955,2	2451,3	2403,6	
	- district heating	1423	1392,7	1192,1	
	- district cooling	177,5	238,6	908,3	
	Renewable energy (kWh/FTE)	2.196,8	2.703,0	3.211,5	
	- electricity	1955,2	2451,3	2403,6	
	- district heating	85,4	41,8	35,8	
	- district cooling	156,2	209,9	772,1	
	Energy produced on site	0	0	0	
Materials	Printing paper (n A4 sheets/FTE/working day)	3,3	3,0	3,5	<15
Water	Annual water use (m^3/FTE)	4,1	6,8	8,2	<6,4
Waste	Total waste (kg/FTE)	47,3	62,5	69,3	<200kg
	Paper (kg/FTE)	5,7	6,3	6,6	
	Plastic (kg/FTE)	0,9	0,5	1,3	
	Glass (kg/FTE)	1,4	3,7	4,2	

	Food (kg/FTE)	15,6	15,6	15,9	
	Confidential (kg/FTE)	1,9	2,3	2,2	
	Non-recyclable (kg/FTE)	21,8	34,2	39	
Emissions to air	Emissions from building (KCO^2/FTE)	246	289,6	298,8	
Emissions to air	Total (KCO^2/FTE) from travel	0,9	904,7	1.815,4	
	- Delegates travel	0,9	759,2	1534,9	
	- Staff missions	0	145,6	280,6	
Emissions	Emissions of CO_2, CH_4, N_2O, HFCs, PFCs, NF_3 and SF_6, expressed in tonnes of CO_2 equivalent	246,9	1.194,4	2.114,3	

9. Legal and Other Obligations of the European Medicines Agency

The EMA is obliged to comply with a range of environmental requirements at local, national, and European levels applicable to its scope of activities. To fulfil and monitor its compliance register, EMA has set up a compliance register to be kept updated on an annual basis.

The register includes requirements for each of the environmental aspects and the obligations on the Agency to comply as well as information of the compliance status.

A significant part of EMA's compliance obligations relates to the building maintenance and related services, which is under the responsibility of the Host State, in line with the lease agreement and Service Level Agreement in place between EMA and the Host State.

The register includes the requirements covered by, among other, the following regulations:

- Environmental permits;
- Environmental management;
- Waste management;
- Energy efficiency, energy efficiency of buildings;
- Water, wastewater, drinking water, management of water systems;
- Regulation related to soil protection and ground water;
- Hazardous materials and products;

- Fluorinated greenhouse gases;
- Air emissions.

The most relevant legal acts are the Dutch Environment and planning Act (Omgevingswet) implemented as of 1 January 2024, the Environmental Management Act and the Energy Savings Act.

The main legal obligations applicable to the Agency are presented in the table below

Environmental aspect	**Compliance obligation**
Soil	Conditions for storing oil and waste oil, used in diesel tank at the EMA building, in aboveground storage tank
Air	Inspection regime, air emissions limit, measurement of air emissions, maintenance of combustion installations i.e. diesel generator Inspections, maintenance, repairs, decommission and leak tightness control and proper documentation of the cooling installation
Energy	Energy efficiency of the building confirmed with an energy label, to be at least label C for office buildings in the Netherlands
Water	Requirements for discharge of water used in the premises Discharge of wastewater from food preparation and prevent odour nuisance associated with food preparation – to be observed by catering provider at the EMA building
Noise	Noise standards for installations and activities in and around the facilities
Hazardous materials	Use of radiation and radioactive substances
Hazardous products	Conditions in which hazardous substance, such as cleaning products, must be stored, storage of safety data sheets of chemicals
Waste	Proper separation of waste, including hazardous waste separation, obligation of waste registration

The compliance register is periodically reviewed.

The Agency also maintains a procedure for emergency response for recording any environmental or other warnings or prosecutions within its Environmental Management System Manual**.**

At the moment the Agency is compliant to all legal requirements related to the environment.

10. Communication

Staff and stakeholder involvement are essential for the success of implementing an environmental management system since the behaviours of the organisation staff, visitors and governance body will have an impact on the outcome.

The environment management activities and coordination of the EMA EMS are part of the Advisory Function for Institutional and Policy (AF-IP) matters with the Head of AF-IP as senior management representative to Environmental Management, as well as sponsor to the EMA Green Group.

In parallel with the implementation of the EMS the Green Group have continued their activities via communication over the 'Go Green with EMA' Viva Engage site, on the EMA intranet Green Initiatives microsite and on the info-screens that are available on all floors in the EMA building. There has also been campaigns and topics raised by operational entities or individual staff members for raising awareness and increase staff involvement.

The initiatives and support activities by the Green Group, operational entities and individual member of staff in 2023 include:

- awareness of the use of antiparasitic in pets

- promotion of tool to calculate individual carbon footprints

- disposal of cooking oil

- waste management and recycling

- promotion of using reusable cups

- Earth Hour

- Awareness of the EU "3 billion trees pledge"

- Bike-to-work week

- reduce food waste

- sustainable social activities

- awareness of pollination insects – balance between honeybees and other species

- campaigns at the EMA building by collaborating with the catering services to offer theme menus for raising awareness with vegetarian/vegan days and other sustainable food promotional days.

The Green Group prepares a plan for suitable topics to communicate and raise awareness of ahead of each year. The plan is further developed over the course of the year to capture relevant events and topics as they occur.

The EMA Environmental Management activities and outcomes were presented to staff and delegates via poster campaigns in March and June 2024.

11. Leadership commitment

Starting September 2023 Senior Managers have visibly demonstrated their strong support, leadership and commitment to environmental management and implementation of sustainability focus at EMA through communication activities with personal blogs and info-screen messages focussing on different topics where EMA have a direct and indirect environmental impact. Topics include supporting the EU Green Deal and what that means to the Agency, sustainable administration, sustainable commuting, importance of clean water, business travel versus virtual participation, waste management and sustainable food with connection to the farm-to-fork initiative and sourcing of local food.

The senior management communication activities continued also in 2024.

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Environmental Statement 2023

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