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# **Report from the Quality Manager**

48<sup>th</sup> Meeting of the Management Board 14-15 December 2017

### Key message

The Management Board is invited to take note of the Quality Manager's annual report outlining the progress made in 2017 with the ISO 9001:2015 (Quality Management Systems) and ISO 14001:2015 (Environmental Management Systems) certifications of ECHA's Integrated Management System.

The Agency successfully passed in October 2017 the re-certification audits.

## Background

The Agency implements an Integrated Management System (IMS) in accordance with the multiannual and annual work programmes. The IMS supports the implementation of the Agency's strategy and provides means to facilitate the effective and efficient management and operation of ECHA.

Since December 2014, the ECHA's IMS is certified according to the internationally recognised standard ISO 9001:2008. The initial scope of certification covered the Agency's tasks under the REACH and CLP regulations and the development of supporting IT applications. In 2015, the scope was extended to PIC and ECHA was the first organisation in Finland certified by the Certification Body for the new standard ISO 9001:2015.

In 2016, the scope of certification was extended to ECHA's tasks under the Biocidal Product Regulation (BPR), and the initial ISO 14001:2015 certification of ECHA's environmental management system.

### Rationale

### Recertification according to the ISO 9001:2015 and ISO 14001:2015 standards

The auditors of the Certification Body confirmed that the Agency continues to fulfil the requirements of the ISO 9001:2015 and ISO 14001:2015 certifications.

The overall outcome of the audit was very good. The auditors positively remarked the continual improvement at organisational level and highlighted in particular, management commitment, skilled staff, structured ways of working, procedures and tools and improved website.

No nonconformity was raised in connection with the environmental management system certification. The auditors identified only one new minor nonconformity against the ISO 9001 requirements which was related to the document approval in the restrictions process. The last year's finding related to the handling of nonconformities and corrective actions remained open. The auditors concluded that the overall situation did not improve despite the actions taken in the course of the year. In addition, some development items were identified for the attention of management.

According to the applicable certification rules, the Agency has to resolve both minor nonconformities within six months at the latest, and according to an action plan agreed with the Certification Body. The next regular surveillance audit will take place in Q4 2018.

The recertification is awarded for a period of three years. The renewed certificate will expire on 14 December 2020. The Certification Body will perform in 2018 and 2019 the regular annual surveillance audits.

### Main developments of the Integrated Management System in 2017

The internal improvement initiative 2016-2017 for reshaping the Quality Assurance Officers network is nearly concluded. The objective was to improve the effectiveness of the network and the efficiency of its working practices. In 2018 the focus will be on consolidating the improved structures and practices and sharing of experience across the Agency.

The implementation of a dedicated IT tool supporting key management system elements is progressing. The first module for the administration, review and approval of documentation is in use across the Agency and has received positive feedback from the users. The second module supporting the handling of NC-CAPA ("Non conformity Corrective Action and Preventive Actions") cases and risk management is under development.

The internal quality auditors, trained in 2016, contributed to the implementation of the Agency's annual Internal Audit Programme and gained first practical auditing experience in the course of 2017.

The review of key elements of the management system is in progress, considering possible adaptations needed for accommodating the Agency's strategic development beyond the 2020 horizon.

In line with ECHA's own Mission and Values, several projects and initiatives supported the achievement of the Agency's environmental objectives aiming at a careful use of natural resources in day-to-day work. The Agency's ISO 14001:2015 compliant environmental management system is the basis for a potential EMAS registration, according to the recent recommendations of the Court of Auditors<sup>1</sup> to EU institutions and bodies.

The Agency continues to actively contribute to the subnetworks of the EU Agencies Network, namely the Performance Development Network and the Greening Network. In June 2017, ECHA hosted the 11th meeting of the EU Agencies Greening Network, bringing together agencies' representatives in the field of environmental management and sustainability.

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<sup>&</sup>lt;sup>1</sup> European Court of Auditors Special Report N° 14/2014, How do the EU institutions and bodies calculate, reduce and offset their greenhouse gas emissions?