POLICY ON STANDARD OPERATING PROCEDURES

(Document endorsed by the Management Board)

ECHA's Policy on Standard Operating Procedures ("SOPs")

1. ESTABLISHING A SOP POLICY FOR ECHA

1.1. SOPs in ECHA's Quality system

The "Quality Plan" presented to the Management Board on 16/10/2007[1] outlined the main features of the Integrated Quality Management System (IQMS), which the management of ECHA decided to set up from the beginning on of the Agency's operations. This system is based on the ISO 9000 standards framework, according to which SOPs constitute the 3rd level of documentation of the IQMS[2]. SOPs can be of vertical (procedure confined to an activity) or horizontal nature (applicable to part or all activities in a certain context).

1.2. Relevance of SOPs in the start-up phase

SOPs are the core of the IQMS of ECHA, at least in its starting years, because:

• Procedures are all to be created *ex nihilo* taking into account both a new legislation (REACH) and new structures (ECHA);

• During the start-up phase the staff will grow rapidly, and the turn-over will be high in 2008 (due to the departure of secondees from the European Commission), hence the necessity to ensure a smooth knowledge transfer;

• The REACH processes are complex and involve by nature different parts of the organisation, hence the need for coherence and well-thought coordination to ensure a high through-put of dossiers in a standardised way;

• The operations of ECHA should be transparent to demonstrate for example the equal treatment of all registrants; a fault in the IQMS would mean higher risk exposure for ECHA;

• If need be, the time pressure that ECHA is facing imposes both the formalisation and the standardisation of operational processes.

ECHA's objective is that **SOPs for key processes will be ready well ahead the entry into operation** of the Agency.

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[1] See MB/19/2007; the Board endorsed the decision by adopting the Work Programme 2008 which includes the first milestones of the project.

[2] Hierarchical documentation, section 4.2.1. of the ISO 9001 standard regarding the proper documentation of procedures.

1.3. Project organisation

Based on some preliminary work, an Agency-wide task force on SOPs, involving representatives of each Directorate, the "Quality Control" (QC) function and the Legal team, has been created on 08/01/2008. The mandate of this task force, which is currently led by QC, is

- to come up with concrete proposals regarding the development of SOPs,

- to exchange ideas among Directorates on the mapping of processes and the development of SOPs, and more generally on the implementation of IQMS and related expectations;

- to relay effectively messages on Quality across the Agency in a view to gain a broad adherence to the project among all levels of staff.

By "mapping processes", it is intended to take stock of all relevant processes in each organisational unit with the view to identify

- sub-processes (i.e. a hierarchy among processes) and

- those processes which are managed, or likely to be managed, by different organisational units, either alternatively (overlapping processes) or cross-functional (horizontal processes).

This work will provide an overview in order to reduce the number of SOPs, avoiding duplications and risks of inconsistencies.

2. MAIN FEATURES OF ECHA'S SOP POLICY

2.1. Definitions

SOPs are detailed written instructions to achieve uniformity of the performance of a specific process, which is repetitive and can be standardised. Usually written by specialists, a SOP is therefore a clearly written description of how a series of tasks is to be performed. SOPs are critical for standardising processes, ensuring that regulatory and organisational policy requirements are met, but also for training personnel and managing workload.

Following this definition, non-routine tasks, e.g. those performed one time only, will not be managed by SOPs.

At a later stage in the implementation of this policy, it may be considered to distinguish specific (sub-)processes of less relevance in terms of staff involvement but that would require to be described with a higher level of detail, and to develop for them Working Instructions ("WINs").

2.2. Scope/ level of detail

Only internally used procedures will be managed by SOPs. In case of processes going over to an external body, only the interface with the external processes should be described in the relevant SOP(s).

The involvement of the Agency's Committees is an integral part of some of the REACH processes. Therefore, some SOPs may be developed to cover those operating procedures which are needed in the Committees or the Forum, but not directly covered in their Rules of Procedure with the appropriate level of detail.

ECHA is going to manage a number of processes which can fall under the responsibility of several organisational units or Directorates,

- be it because the responsibility may change hands one or several times within the same individual process (e.g. dossier and substance evaluation, Annex XV dossiers),

- be it because the same process by nature is managed by the one or the other unit or Directorate, depending on certain conditions (e.g. draft decisions).

In those cases, the rule should be that a single SOP has to be drafted, adopted and implemented on a common basis. This option goes together with the principle that the SOP should not go beyond a level of detail which makes it understandable by all potential users.

2.3. Legal compliance

A sound legal risk management in view of a strict compliance of all processes and outputs with REACH and other applicable regulations is a key element of ECHA's strategy and the main condition of its credibility. Ensuring that SOPs comply with REACH mitigates the risk that decisions and opinions, which should result from the observance of the SOPs, will be challenged by appeals or Court proceedings, or that the Agency's competence be publicly questioned (reputational risk).

Therefore, all new SOPs will be subject to a legal check.

2.4. Transparency

ECHA's general communication policy includes the commitment of transparency on the Agency's work, rules and procedures, in the spirit of REACH and of the Regulation on public access to documents[3]. Well applied, this principle of transparency is a key factor to demonstrate the equal treatment of all registrants (see above). Following this, SOPs should be accessible to the public on ECHA's web-site to the extent that it is appropriate.

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[3] Regulation (EC)1049/2001 of 30/05/2001, applicable to ECHA through REACH Art. 118

2.5. Training and communication

The objectives of the SOPs should be very clear to all ECHA staff, in particular when writing them. The relating training and communication strategy comprises:

- a regular communication on Quality and Internal Control (IC) at the General Staff Assembly,

- a "QM and IC Standards" module introducing the corresponding training offer by the Commission;

- a half-day in-house training for all staff[4], with the following objectives: broad understanding of ECHA's IQMS (including the respective roles of the different actors of IQMS within ECHA); purpose, addressees of SOPs and how to use them; how to write a SOP;

- The use of the SOP task force (see above) as a "multiplicator".

3. MANAGING THE SOP LIFE CYCLE

The following elements will be explained in more detail in a specific "meta-SOP" ("preparation and approval of new SOPs") which will be part of ECHA's Quality Manual. This SOP will be subsequently complemented by further SOPs related to revision or withdrawal.

3.1. Template

SOPs that follow a systematic format allow ECHA staff to find information quickly and therefore perform the tasks faster and more accurately. Therefore, a common template should be made compulsory for all SOPs Agency-wide.

3.2. Drafting

SOPs should be written by staff directly involved in the process to be described. Their language should be understandable by all actors dealing with the process.

3.3. Testing

SOPs should be tested by two different persons, who did not participate in its writing. Writers and testers should therefore be identified in advance.

3.4. Legal check

The legal check will be performed by ECHA Legal team (see above), depending on the estimated relevance and level of compliance risk.

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[4] Currently in preparation

3.5. Release

SOPs must be checked for compliance with the Quality Policy before approval. They are finally formally approved by the Executive Director, in order to avoid the circulation of drafts or unauthorised alterations.

3.6. Administration

The necessary administration of SOPs encompasses the management of templates, easy numbering, identification of history and current status of a SOP, filing and archiving.

3.7. Distribution

The administration of SOPs should take place, as much as possible, in a paperless environment. To this aim, ECHA chose to use MS sharepoint as Document Management System (DMS). It is foreseen that an application of the DMS will be dedicated to the maintenance of SOPs.

3.8. Publication

The process owner should make a recommendation to the Executive Director to make the SOP public or, with justification, to limit its access (see above). After a SOP is released without restriction of access, the publication on the ECHA website takes place centrally.

3.9. Translation into operational workflows

It is ECHA's general policy to use IT tools, as far as possible, to manage electronically the operational workflows linked to the execution of key SOPs. The related programming and testing activities are not part of the SOP itself5.

3.10. Training (on individual SOPs)

While SOPs are a powerful tool for controlling activities and increasing the reliability of processes, they cannot replace appropriate trainings and the opportunity of dialogue. This kind of training should take place immediately after a SOP is released.

3.11. Deviations

Deviations must be documented as such and duly authorised. If the cause of deviation is the SOP itself, this should trigger a revision process.

3.12. Alteration

SOPs should be regularly reviewed and updated. A secured system of change control and rights to modify SOPs should be put in place, also with the view to ensure the proper audit trail.

3.13. Review

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[5] But of course the design of associated reports and the definition of potential performance indicators are other elements of the Quality system and Quality policy.

The set of SOPs should be subject to a periodical management review, which can result in updates and revision. Independent audits should take into account the SOP life cycle and the risks associated to its implementation.