Dossier Evaluation

1. Purpose

The purpose of this procedure is to describe the dossier evaluation process, which includes Compliance Check (CC) and Testing Proposal (TP) Examination, as stated in the REACH Regulation (Title VI).

This procedure is designed to ensure that

• dossier evaluation is based on sound and consistent scientific judgement,

• requests for further information that may result from dossier evaluation are consistent, scientifically robust and legally sound,

• legislative deadlines are respected,

• internal requirements for efficient dossier evaluations are met.

2. Scope

This procedure begins either when a dossier containing a TP has been registered (for TP examination) or when a registered dossier has been selected for compliance check (for CC). This procedure ends either after 1) a termination letter or a conclusion with no action is approved, 2) the registrant has met the requirements of the Draft Decision (DD) in a dossier update submitted before referral of the DD to the Member States Competent Authorities (MSCAs), or 3) the follow-up of an ECHA Evaluation Decision is completed.

Linkage to ECHA Process System

L1. Activity:	2 Evaluation
L2. Process:	2.1 Dossier evaluation
L3. Sub-process:	2.1.1 DEG Planning and Monitoring 2.1.2 Examination of Testing Proposals 2.1.3 Compliance Checks 2.1.4 Processing of Draft Decisions

3. Description

Dossier evaluations are subdivided into Compliance Checks of registration dossiers (Article 41) and Examinations of Testing Proposals (Article 40). Both processes follow the same

decision making process (Articles 51 and 52). The information provided in the dossiers is assessed with regard to adequacy and completeness. The MSCAs take part in the decision making process and are informed on the status and outcome of the evaluations at specific points in the process.

In case the evaluations result in requests for further information to be provided in updated dossiers, the submitted new information is evaluated versus the initial request in a follow-up process (Article 42).

Dossier evaluation is divided into four stages.

Pre-processing

The tasks performed in this stage are associated with preparing the dossiers for evaluation, selection of dossiers, assigning roles to evaluation staff, obtaining chemical identity and profiling information and third party consultation where required.

Scientific and legal processing

This stage takes the dossier and, where relevant, information provided by third party consultation, through scientific and legal analysis and either produces a termination letter, a Quality Observation Letter (QOBL) and/or Draft Decision (as well as accompanying notification letter), or a conclusion with no action.

Processing of Draft Decision (DD)

At this stage, after consultation with the registrant and the MSCAs, a DD becomes an ECHA Evaluation Decision. If the MSCAs propose amendments to the DD, this will be achieved either by unanimous agreement in the MSC, or, if unanimous agreement is not reached, by the Commission.

Follow-up

At this stage an updated dossier, referring to the decision requesting for further information with a set deadline/target date, is expected from the registrant. The dossier will be re-evaluated and the Director will decide on the course of action.

The dossier may be updated at any point by the registrant. If the updated dossier contains scientific relevant data or important administrative changes, a decision will be made on how to proceed. The update of the dossier may lead to the (ongoing) procedure being terminated and (if applicable) a termination letter being issued. Dossier updates submitted by registrants after referral of a DD to MSCAs cannot be taken into account in the further decision making process.

3.1. Pre-processing of the dossier

Step 1 - Identify dossiers for CC or TP and prepare for evaluation

To be available for evaluation the dossier must have passed through the registration pipeline and been stored in the production IUCLID database as described in the procedure on Dossier Processing. All registered dossiers containing TPs (i.e. identified in the endpoint study record by selecting ‘experimental study planned’ in the field ‘study result type’ in the IUCLID dossier) are selected for TP examination. Dossiers with non-phase-in substances or requiring third party consultation for proposed vertebrate animal testing are prioritised. Dossiers are selected for CC both randomly and concern-driven. The concern

driven selection aims to address specific endpoints or information requirements that may have an immediate impact on the safe use of a substance. The concern-driven selection is assisted with an IT-based filtering algorithm.

Once selected, dossiers are assigned to a Dossier Evaluation Group (DEG). Where applicable, specific DEG expertise is considered in the assignment process. Another DEG is selected for conducting the quality check. The assignment of staff members involved in the evaluation of a dossier is performed following internal procedures that implement the Policy for Managing potential Conflicts of Interests (CoI) (MB/45/2011 final). The administrative start of the dossier evaluation is performed.

Step 2 – Substance identity check and chemical profiling

The dossiers are checked against the information requirements related to the identification of the registered substance as laid down in Annex VI – section 2 of the REACH Regulation (by the Substance identity and data sharing Unit).

The physico-chemical properties, environmental fate, aquatic toxicity and toxicological properties of the registered substance are predicted by using computational tools (by the computational assessment Unit). Possible environmental or toxicological concerns are predicted based on the structure of the substance. Chemical profiling also includes information from publicly available international assessments, if any was performed for the registered substance.

Step 3a - Inform MSCAs

For TPs, the Member States Competent Authorities (MSCAs) are informed of the initiation of the TP examination.

Step 3b - Third party consultation

When a TP includes vertebrate animal testing, information relating to the TP is published on ECHA's website. This includes details on the identity of the substance proposed to be tested, the hazard endpoint for which testing is proposed, as well as start and end dates for the third party consultation. Third parties are thereby invited to submit scientifically valid information and studies within 45 days of the date of publication.

3.2. Scientific processing of the dossier

Step 4 - Scientific and legal evaluation

The DEG evaluates the dossier. In their scientific judgements, the DEG members consider whether the information provided in the dossier meets the information requirements of the REACH Regulation. For the scientific part of the evaluation, standard questions and instructions are used to systematically identify shortcomings in dossiers. The DEG conclusions on such shortcomings can be converted into legal documents requesting further information from the registrant. This requires that the scientific judgements are based on detailed expert knowledge and are legally sound. Measures for ensuring consistency in the scientific and legal judgement include advice on specific scientific issues by senior scientific staff and advice on legal issues by legal advisors.

For a CC, the DEG either evaluates all the endpoints in the dossier including the chemical safety report (CSR) or targets the evaluation to a certain limited part of the dossier e.g. to the information on adverse effects or specific parts of the CSR.

For a TP, the DEG assesses the grounds for conducting the proposed test taking into account the dossier information and all relevant scientifically valid information received from third parties during third party consultation, if conducted. In this context other closely related endpoints to the test proposed can be examined.

Step 5 - Scientific quality check

The Quality Check (QC) reviewers verify that the systematic approach for scientific and legal dossier evaluation has been followed. In addition, the QC reviewer checks whether the findings are scientifically accurate, clearly reported and consistent with previous conclusions.

Step 6 - Internal recommendation for Director's decision

The outcome of the scientific and legal evaluation is discussed between scientific and legal staff and the management. All participants involved in the discussion shall declare any potential CoI. The result of this discussion is a recommendation for the Director's decision on how to proceed, *i.e.* the appropriate option for addressing the findings identified during the dossier evaluation: Draft Decision, quality observation letter, other letter or no action. For CC, the decision to officially open the process is confirmed. A TP examination will always result in an ECHA decision, unless the TP is deemed invalid by ECHA or withdrawn by the registrants prior to referral to MSCAs.

Step 7 - Inform MSCAs

The MSCAs are informed of the initiation of CCs. Within 12 months of this date, the CC procedure will be concluded with a conclusion of no action or a Draft Decision where applicable. Moreover, a QOBL may be issued, alone or in combination with a Draft Decision.

Step 8 - Approve conclusion with no action

This step is only performed for CCs where no formal action towards the registrant is deemed necessary.

In this case, the procedure is completed and the MSCAs are notified.

Step 9 - Prepare outcome document

Steps 9 to 11b are performed when action towards the registrant is deemed necessary

Any shortcomings/findings identified during the CC/TP evaluation are addressed in the appropriate outcome documents according to the internal decision recommendation made.

Step 10 - Legal verification and quality check of the outgoing document

The content of the outgoing document to be sent to the registrant(s)/DU(s) is reviewed by the legal team, and checked for consistency with the recommendation for Director's decision.

Step 11a – Approve Draft Decision and sign notification letter

Following the legal verification, the Draft Decision and its accompanying notification letter are finalised by the Scientific Dossier Manager (SDM), reviewed by the Head od Unit (HoU) and approved by the Director. The notification letter is signed by the Director.

Step 11b - Approve, sign and send the Quality Observation Letters or other letters

This step is only applicable for CCs.

The Quality Observation Letter (QOBL) or other letters are finalised by the SDM, reviewed by the HoU and approved and signed by the Director (or their delegates), then sent to the registrant(s)/DU(s). The QOBL is also notified to the MSCAs. The QOBL invites the registrant to update his dossier with further information and contains a target date by which the registrant is expected to submit an updated dossier.

3.3. Processing of the Draft Decision

Step 12 - Notify Draft Decision to the registrant(s)/DU(s)

The Draft Decision and the signed letter for notifying the registrant(s) or the DU(s) that a CC has been conducted and resulted in a Draft Decision are sent. Where appropriate, the original third party response(s) received during third party consultation are also provided to the registrant/DU(s). The registrant(s)/DU(s) is/are notified in the notification letter of their right to comment on the Draft Decision within 30 days starting from the date the Draft Decision was sent, and an update of the dossier may be submitted.

Step 13 - Examine registrant(s)/DU(s) comments

If comments were provided by the registrant(s)/DU(s), a response to each comment is prepared by the DEG and recorded. The Director decides whether the Draft Decision should be amended on the basis of the comments/additional information provided by the registrant(s)/DU(s). If the Draft Decision is amended, a legal verification is performed.

For CC, if the comments and the subsequent updated dossier provided by the registrant(s)/DU(s) are considered to meet all requests in the Draft Decision, the DD is withdrawn and the CC concluded with no further action. A letter signed by the Director is sent to the registrant(s)/DU(s) to inform him/them of the conclusion on the CC. MSCAs are informed.

If no comments are received from the registrant(s)/DU(s) within the 30-day commenting period, the Draft Decision is not amended.

Step 14 - Notify (amended) Draft Decision to the MSCAs

The (amended) Draft Decision is notified to the MSCAs. Additional documents including, where appropriate, the third party response(s) obtained during third party consultation, the original comments from the registrant(s)/DU(s), the responses to these comments and the registration dossier are also provided to the MSCAs. The MSCAs can submit proposals for amendments of the Draft Decision within 30 days starting from the date they were notified of the Draft Decision.

Step 15 - Examine MSCAs' proposals for amendments

If no proposals for amendments are submitted by the MSCAs, the procedure continues at Step 19b.

Where proposals for amendments are submitted by the MSCAs, *the procedure continues at Step 16 and* the Draft Decision is referred to the MSC to seek a unanimous agreement. Furthermore, a response to each proposal for amendment is prepared by the DEG and recorded. The Director decides whether the Draft Decision should be amended on the basis of the proposals for amendment provided by the MSCAs. If the Draft Decision is amended, the amended document is checked for legal correctness.

Step 16 - Communicate MSCAs' proposals for amendments to the registrant(s)/DU(s)

If a proposal for amendment is received, the Draft Decision as notified to the MSCAs, the MSCAs' proposals for amendments and a cover letter in charge of the dossier are sent to the registrant(s)/DU(s). The cover letter notifies the registrant(s)/DU(s) of his/their right to comment on the MSCAs' proposals for amendments over a 30-day period starting on the day the documents are sent to the registrant(s)/DU(s).

Step 17 - Refer to the Member States Committee (MSC)

If a proposal for amendment is received, the dossier is referred to the MSC-S who formally starts the 60 day period for seeking agreement within the MSC. The MSC-S refers an (amended) Draft Decision, together with any amendments proposed, to the Member State Committee no later than 15 days after the end of the 30-day MSCA commenting period. In addition, the MCS-S refers all registrant's comments regarding the Draft Decision.

Step 18 - Examine registrant(s)'/DU(s)' comments on the proposals for amendments

The comments from the registrant are recorded and the MSC-S is informed of the registrant's comments.

Step 19a - Adopt the ECHA Evaluation Decision

An ECHA Evaluation Decision can be reached in two cases: if no proposals for amendments of the Draft Decision were submitted by the MSCAs or if a unanimous agreement is reached by the MSC*. In these cases, the (amended) Draft Decision is adopted and becomes the ECHA Decision.

*Note: At the end of the MSC's deliberation the MSC-S records the result which will either be an ECHA Decision, or a notification that the MSC could not reach a unanimous decision.

Step 19b - Refer to the Commission

Where unanimous agreement could not be reached by the MSC, the dossier is referred to the Commission. A letter is sent to the registrant(s)/DU(s) to inform him/them that the case has been referred to the Commission.

Step 20 - Notify ECHA Decision to the registrant(s)/DU(s)

The ECHA Decision is notified to the registrant(s)/DU(s). The ECHA Decision is also notified to the MSCAs. The ECHA Decision will usually request further information to be provided by the registrant in the form of an updated dossier by a deadline date. In some cases, *i.e.* rejection of a testing proposal, no further information is required, no deadline is necessary and no follow-up is foreseen. The registrant is also notified of his right to appeal against this decision to the Board of Appeal of ECHA within three months of receiving notification of this decision.

Step 21 - Publish information on the ECHA website

A non-confidential version of the Dossier Evaluation decisions is published on the ECHA website. ECHA's responses to the third party comments received during third party consultation for TP are included in the ECHA Decision. However, confidential information will not be published.

3.4. Follow-up of Dossier Evaluation Decisions

The follow-up stage occurs after the deadline/target date for a request for further information has passed. This request may originate from ECHA under REACH Regulation or from MSCAs under NONs Directive.

Step 22 - Targeted evaluation of updated issues

A dossier evaluation occurs similar to the one described in Step 4 Scientific and Legal Evaluation. This evaluation is however targeted to the information requested in the TP or CC ECHA Decision.

Step 23 - Internal recommendation for Director's decision

The outcome of the targeted evaluation is discussed between scientific and legal staff and the management. The result of this discussion is a recommendation for the Director's decision on how to proceed, *i.e.* to send either a statement of non-compliance with the decision (Article 51) or an Article 42(2) notification. An additional or alternative recommendation might be to initiate another CC (Article 42(1)). In this case the outgoing documents for the issues of the first CC may be put on hold until the new CC is under follow up examination.

Step 24 - Prepare outcome document

The outcome document will be prepared by the SDM in agreement with the internal recommendation. The content of the outcome document is reviewed by the legal team, and checked for consistency with the recommendation for Director's decision.

Step 25 - Approve outcome document

The outcome document is finalised by the SDM, reviewed by the HoUs and approved by the Director. If applicable, the outcome document is signed by the Director.

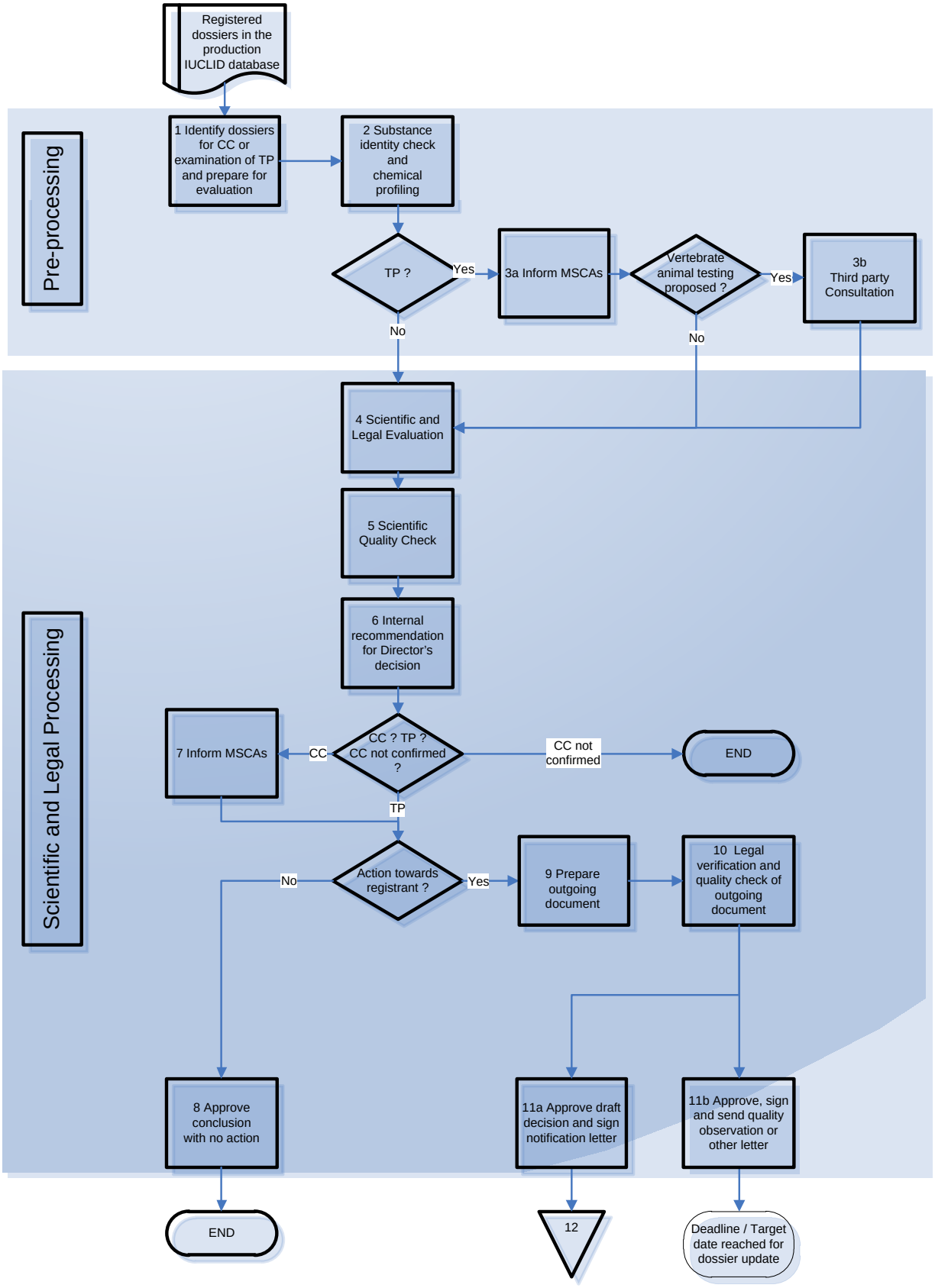
Step 26a – Send statement of non-compliance with the decision

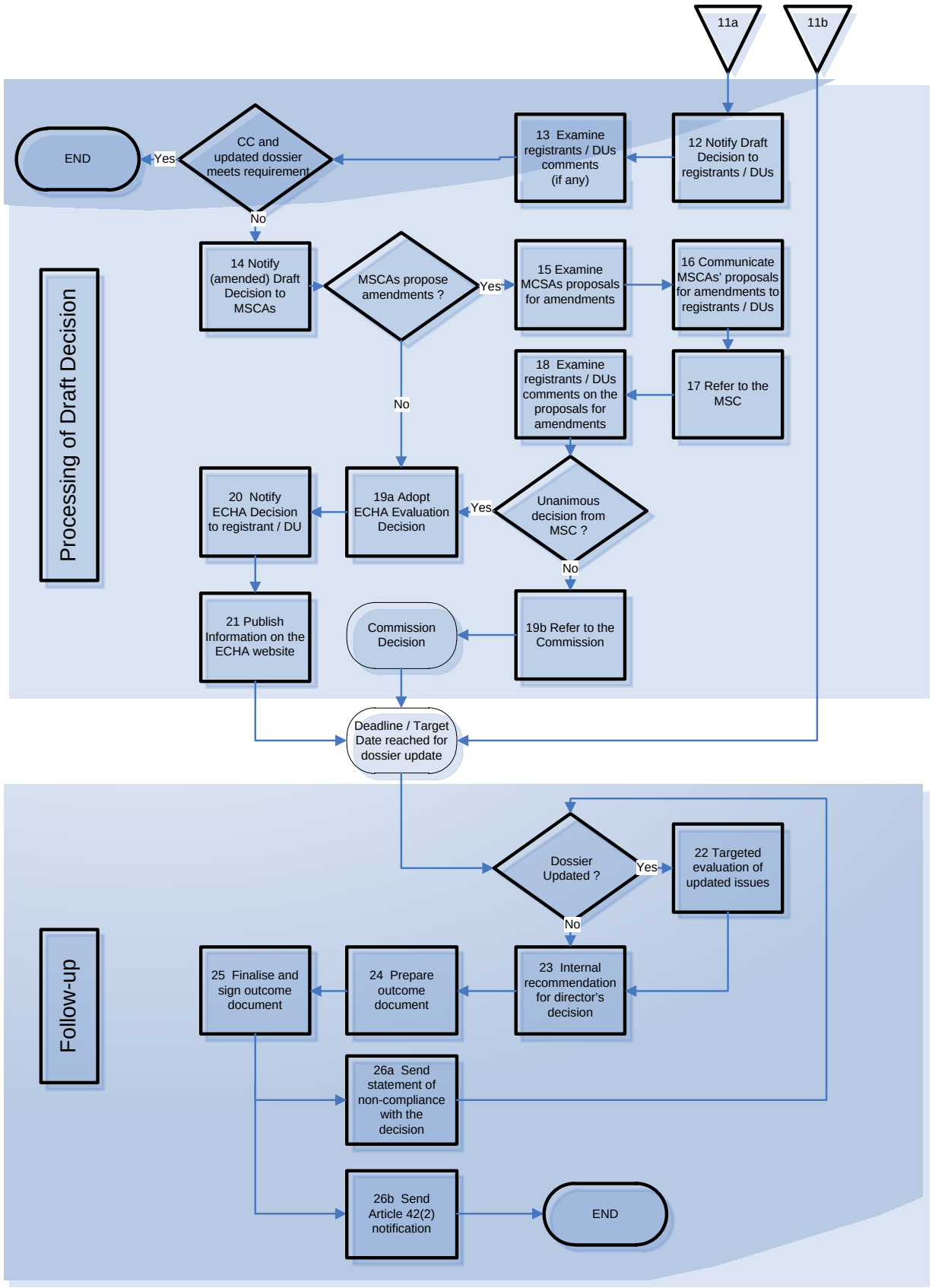
The statement of non-compliance with the decision is sent to the responsible Member State (MS), and a copy to the registrant. By sending this statement of non-compliance, ECHA recommends enforcement of (part of) the ECHA Decision by the National Enforcement Authority. As a result, ECHA normally expects to receive an (updated) dossier that should be submitted again for targeted follow-up examination at a later stage.

Step 26b – Send Article 42(2) notification

The Article 42(2) notification is sent to the MSCAs and the Commission. The Article 42 notification can be regarded as the completion of the dossier evaluation per decision. ECHA will notify the Commission and MSCA on any conclusion made according to Article 42(2). The information in the notification may be used for the purposes of other REACH processes, e.g. identification of CoRAP candidates (Art.44), Substance evaluation (Art.45(5)), Authorisation (Art.59(3)), Restriction (Art.69(4)), or as basis for proposals for harmonised C&L.

4. Flowchart


Registered dossiers in the production IUCLID database
Pre-processing
1 Identify dossiers for CC or examination of TP and prepare for evaluation
2 Substance identity check and chemical profiling
TP ?
Yes
3a Inform MSCAs
Vertebrate animal testing proposed ?
Yes
3b Third party Consultation
No
No
4 Scientific and Legal Evaluation
5 Scientific Quality Check
6 Internal recommendation for Director's decision
Scientific and Legal Processing
7 Inform MSCAs
CC
CC ? TP ? CC not confirmed ?
CC not confirmed
END
TP
No
Action towards registrant ?
Yes
9 Prepare outgoing document
10 Legal verification and quality check of outgoing document
8 Approve conclusion with no action
11a Approve draft decision and sign notification letter
11b Approve, sign and send quality observation or other letter
END
12
Deadline / Target date reached for dossier update


11a
11b
Processing of Draft Decision
12 Notify Draft Decision to registrants / DUs
13 Examine registrants / DUs comments (if any)
CC and updated dossier meets requirement
Yes
END
No
14 Notify (amended) Draft Decision to MSCAs
MSCAs propose amendments ?
Yes
15 Examine MCSAs proposals for amendments
16 Communicate MSCAs' proposals for amendments to registrants / DUs
17 Refer to the MSC
18 Examine registrants / DUs comments on the proposals for amendments
No
Unanimous decision from MSC ?
Yes
No
19a Adopt ECHA Evaluation Decision
20 Notify ECHA Decision to registrant / DU
19b Refer to the Commission
Commission Decision
21 Publish Information on the ECHA website
Deadline / Target Date reached for dossier update
Follow-up
Dossier Updated ?
Yes
No
22 Targeted evaluation of updated issues
23 Internal recommendation for director's decision
24 Prepare outcome document
25 Finalise and sign outcome document
26a Send statement of non-compliance with the decision
26b Send Article 42(2) notification
END

5. Definitions

Term or abbreviation	Definition
BoA	Board of Appeal
CC	Compliance Check
CIRCABC	Communication & Information Resource Centre Administration
CLP	Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (CLP Regulation)
CoI	Conflicts of Interests
CoRAP	Community Rolling Action Plan
CSR	Chemical safety report
DD	Draft Decision
DEG	Dossier Evaluation Group
ECM-DEP	Enterprise Content Management-Dossier Evaluation Process
DU	Downstream User
EC	European Commission
EU	European Union
HoU	Head of Unit
IUCLID	International Uniform Chemical Information Database
MS	Member State
MSC	Member State Committee
MSC-S	Member State Committee Secretariat
MSCA	Member State Competent Authority
NONs	Notified New Substances (Directive 67/548/EEC; considered as registered according to Art. 24 of REACH)
OECD	Organisation for Economic Cooperation and Development
QC	Quality Check
QOBL	Quality Observation Letter

Term or abbreviation	Definition
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH Regulation)
REG	Registrant
SDM	Scientific Dossier Manager
TP	Testing Proposal

6. References

Associated document code	Document name
Regulation (EC) No 1907/2006	REACH Regulation
Directive 67/548/EEC	Dangerous Substances Directive
Regulation (EC) No 1272/2008	CLP Regulation
Regulation (EC) No 440/2008	EU Test Methods Regulation
	Guidance on information requirements and chemical safety assessment
	Guidance on dossier and substance evaluation
	OECD test guidelines
	Guidance for intermediates
	ECHA Practical guide 12: how to communicate with ECHA in dossier evaluation
MB/45/2011 final	Policy for Managing potential Conflicts of Interests (CoI)

IQMS document code	Document name
POL-0005	Internal Classification and Handling of Information and Documents
POL-0015	Dossier Evaluation

WIN-0011	Processing initial requests for access to documents
WIN-0033	Confirmatory Application for Access to Documents Decision
WIN-0054	Substance Profiling for TPE and CC in Dossier Evaluation
WIN-0057	Allocation of profiling tasks
WIN-0076	Dossier Evaluation - Pre-processing
WIN-0077	Dossier Evaluation - Scientific and Legal evaluation of the dossier
WIN-0078	Dossier Evaluation - Preparing outcome documents
WIN-0079	Dossier Evaluation - Processing of Draft Decision
WIN-0080	Dossier Evaluation – Follow-up

7. Records

Record Name/Code	Ref. to Step	Ownership #	Sec. level	Access	Storage location	Comments
Information submitted by the 3rd parties	3	EA*	Internal (Conf.)	Dir.E	ECM-DEP	If applicable
Termination letter	may happen at any stage	EA*	Internal (Conf.)	Dir.E +REG +MSCAs	ECM-DEP CIRCA BC£	If applicable
Quality Observation Letter	11	EA*	Internal (Conf.)	Dir.E +REG +MSCAs	ECM-DEP CIRCA BC£	If step 9 and QOBL apply
Draft Decision	12, 14, 16, 18	EA*	Internal (Conf.)	Dir.E +REG +MSCAs +MSC	ECM-DEP CIRCA BC£	If step 9 and DD apply

Notification letter	12, 14, 16, 20	EA*	Internal (Conf.)	Dir.E +REG +MSCAs	ECM-DEP CIRCA BC£	Sent only with a draft or a final decision
ECHA Evaluation Decision (sent to REG)	19-20	EA*	Internal (Conf.)	Dir.E +REG +MSCAs +BoA	ECM-DEP CIRCA BC£	

Note that all staff of Dir.E have access and may amend the documents.
* Evaluation assistant (EA) of the DEG evaluating the particular dossier.
£ according to CIRCABC retention time limit (Decision by the Director of Evaluation on 3.6.2013: Use of CIRCABC for Granting Member States Competent Authorities, Mandated National Institutions' and the European Commission Access to Confidential and Restricted Information with regard to tasks under Title VI of the REACH regulation).

8. Annexes

N/A

9. Change history

Revision	Changed section	Change description	Date
1		Initial document	20/12/2010
2	All sections	• Use of new template • 3.3: change order of steps 17 and 18 • 3.4: text harmonized with DCM paper on Follow-up (step 22 "Communicate to MSCAs" was deleted; text of steps 22, 23 and 26a 26b (new numbering) where modified) • 4: Flowchart for Follow-up was modified	06/07/2012

3	All sections	• the actors of some actions are removed from the PRO. • 'final decision' replaced by 'ECHA (Evaluation) Decision'. • mention of CoI at several stages of Dossier Evaluation process (e.g. Step 1 - Identify dossiers for CC or TP and prepare for evaluation, Step 6 - Internal recommendation for Director's decision). Policy for Managing potential Conflicts of Interests (CoI, MB/45/2011 final) was inserted as reference document. • 'Conclusion document' replaced by 'Conclusion with no action' • Section 3.1, Step 1: reference to AoC strategy by mentioning 'concern-driven selection assisted with an IT-based filtering algorithm'. • Section 3.1, Step 2: reference to 'international assessments' for the chemical profiling. • Section 3.3, Step 20: mention/reminder of the right of registrant to appeal against an ECHA decision. • Section 3.4, step 23: mention of possibility to initiate another compliance check. • Flowchart: align Title of steps with the text (steps 8, 19a and 20) • Records: 'Sharepoint and/or ECM-DEP' replaced by 'ECM-DEP'.	24/06/2013