What applicants need to know about technical equivalence and chemical similarity

Technical equivalence process

21 March 2014

Virginia Rodriguez Unamuno
Biocides Assessment Unit
European Chemicals Agency

Outline

- What is technical equivalence?
- When is it necessary to establish technical equivalence?
- Who may apply?
- How is the application submitted?

Article 3 – Definitions

(w) " ***Technical equivalence***" means similarity, as regards, the chemical composition and hazard profile, o a substance produced either from a source different to the reference source, or from the reference source but following a change to the manufacturing process and/or manufacturing location, compared to the substance of the reference source in respect of which the initial risk assessment was carried out as established in Article 54"

Substances concerned

- Active substances which have been approved* and included in Annex I of the Directive 98/8/EC or in the Union list of approved active substances (BPR)

(*) *"…applications for technical equivalence are to be submitted after the decision to approve an active substance has been made…"*

Therefore…

Technical equivalence is **ONLY** for approved active substances

Legal requirement under BPR Article 54

Meanwhile…

Chemical similarity service is for active substances for which **the approval process is not finalised** or **has not been initiated**

Service offered by ECHA hence not legally required

Article 54(1) – Assessment of technical equivalence

*"…Where it is **necessary to establish the technical equivalence of active substances**, the person seeking to establish that equivalence ('the applicant') shall submit an application to the Agency…"*

When is it necessary to establish technical equivalence?

The biocidal product contains either:

- An active substance manufactured by the **same manufacturer** whose substance has been assessed for inclusion in the Union list of approved active substances **following a change**:
  - In the manufacturing location;
  - In the manufacturing process.

When is it necessary to establish technical equivalence?

or:

- An active substance from a **different manufacturer** than the one whose substance has been assessed for inclusion in the Union list of approved active substances

Who may apply?

- Active substance suppliers who participated in the Review Programme
- New suppliers of the active substance in the market

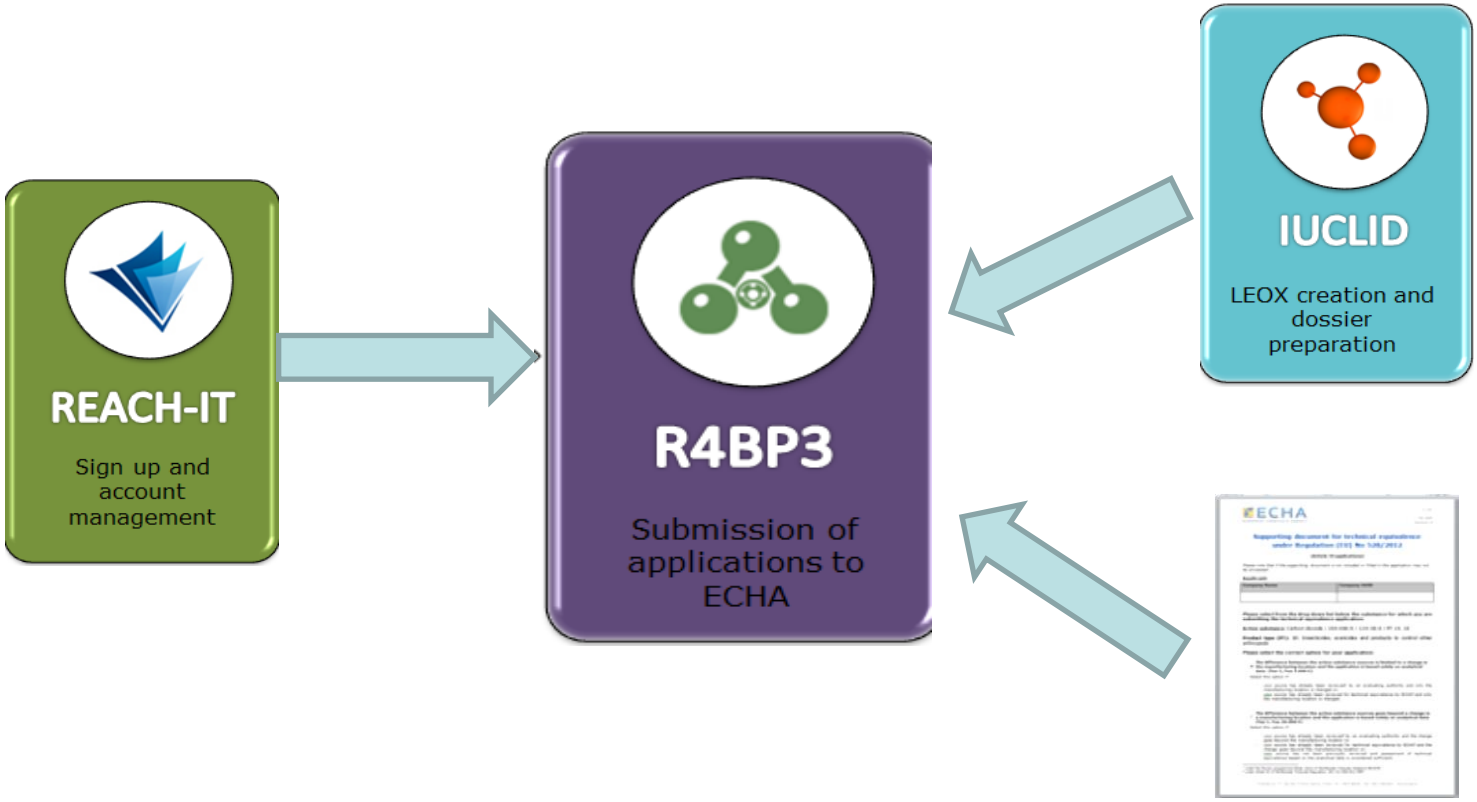
But also…

- Formulators who want to obtain a first biocidal authorisation
- Formulators who want to change the supplier of the active substance for an already authorised biocidal product

Article 54(2) – Assessment of technical equivalence (cont.)

*"…The **applicant shall submit all data** that the Agency requires **to assess technical equivalence**…"*

Technical equivalence applications

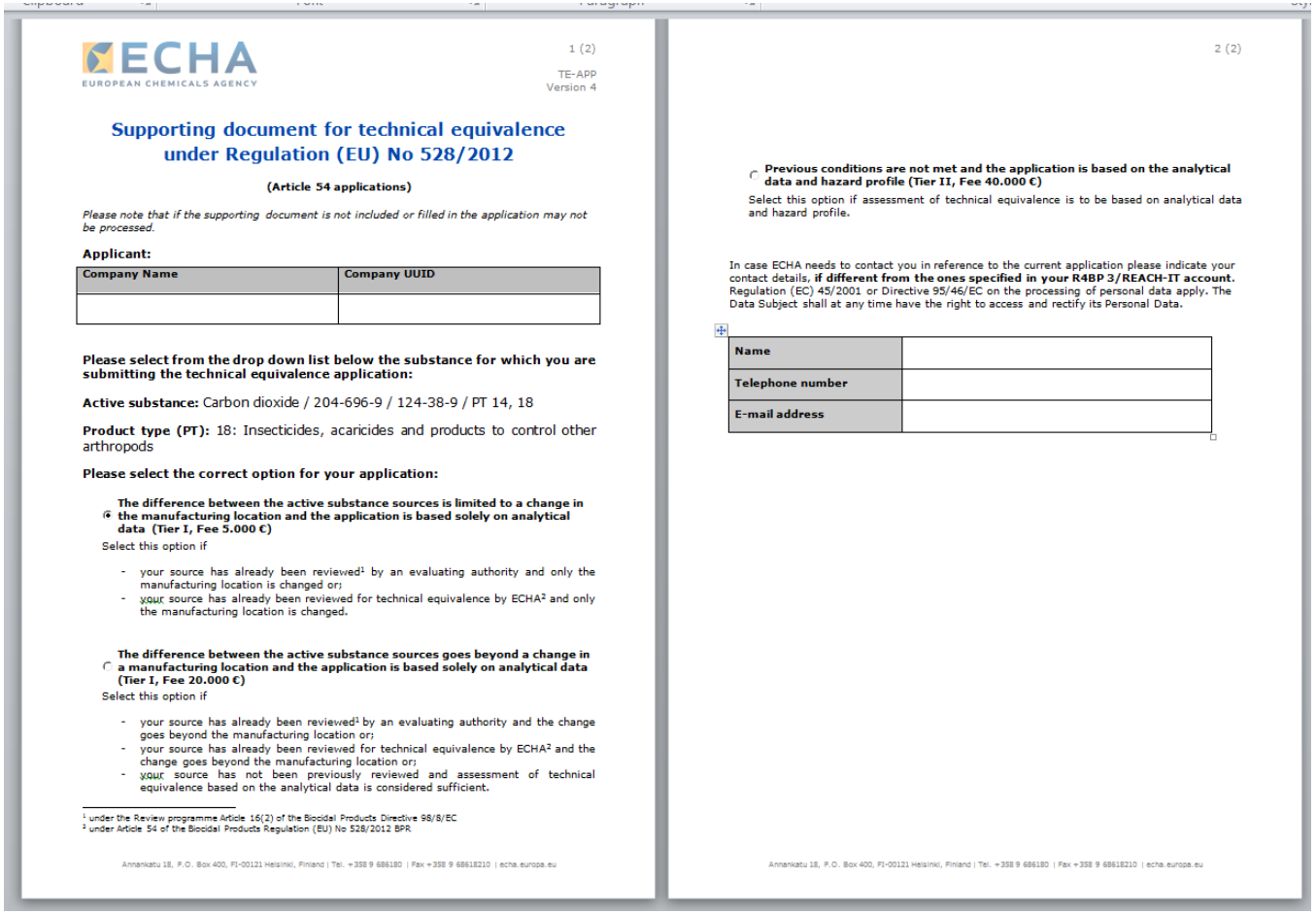


The supporting document

Documents that are required for compliance / to enable processing		
Process	**Supporting document**	**Published on** Please confirm that you are using the latest version of the document template, otherwise your application may not be accepted.
Assessment of technical equivalence	Application for assessment of technical equivalence [DOC]	7 March 2014

http://echa.europa.eu/support/dossier-submission-tools/r4bp/supporting-documents

The supporting document



ECHA
EUROPEAN CHEMICALS AGENCY

1 (2)

TE-APP
Version 4

Supporting document for technical equivalence under Regulation (EU) No 528/2012

(Article 54 applications)

Please note that if the supporting document is not included or filled in the application may not be processed.

Applicant:

Company Name	Company UUID

Please select from the drop down list below the substance for which you are submitting the technical equivalence application:

Active substance: Carbon dioxide / 204-696-9 / 124-38-9 / PT 14, 18

Product type (PT): 18: Insecticides, acaricides and products to control other arthropods

Please select the correct option for your application:

(•) **The difference between the active substance sources is limited to a change in the manufacturing location and the application is based solely on analytical data (Tier I, Fee 5.000 €)**

Select this option if

- your source has already been reviewed[1] by an evaluating authority and only the manufacturing location is changed or;
- your source has already been reviewed for technical equivalence by ECHA[2] and only the manufacturing location is changed.

( ) **The difference between the active substance sources goes beyond a change in a manufacturing location and the application is based solely on analytical data (Tier I, Fee 20.000 €)**

Select this option if

- your source has already been reviewed[1] by an evaluating authority and the change goes beyond the manufacturing location or;
- your source has already been reviewed for technical equivalence by ECHA[2] and the change goes beyond the manufacturing location or;
- your source has not been previously reviewed and assessment of technical equivalence based on the analytical data is considered sufficient.

[1] under the Review programme Article 16(2) of the Biocidal Products Directive 98/8/EC
[2] under Article 54 of the Biocidal Products Regulation (EU) No 528/2012 BPR

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

2 (2)

( ) **Previous conditions are not met and the application is based on the analytical data and hazard profile (Tier II, Fee 40.000 €)**

Select this option if assessment of technical equivalence is to be based on analytical data and hazard profile.

In case ECHA needs to contact you in reference to the current application please indicate your contact details, **if different from the ones specified in your R4BP 3/REACH-IT account.** Regulation (EC) 45/2001 or Directive 95/46/EC on the processing of personal data apply. The Data Subject shall at any time have the right to access and rectify its Personal Data.

Name	
Telephone number	
E-mail address	

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

The IUCLID dossier shall contain:

- Administrative information
- Information on the substance identity
- Study summaries: full description of the studies conducted or referred to the methods used for the required endpoints
- The original test reports or the letter of access to such reports
- Self assessment of technical equivalence in case of Tier II applications

Article 54(3) – Assessment of technical equivalence (cont.)

*"…The **Agency shall inform** the applicant **of the fees** payable under Article 80(1), and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly…"*

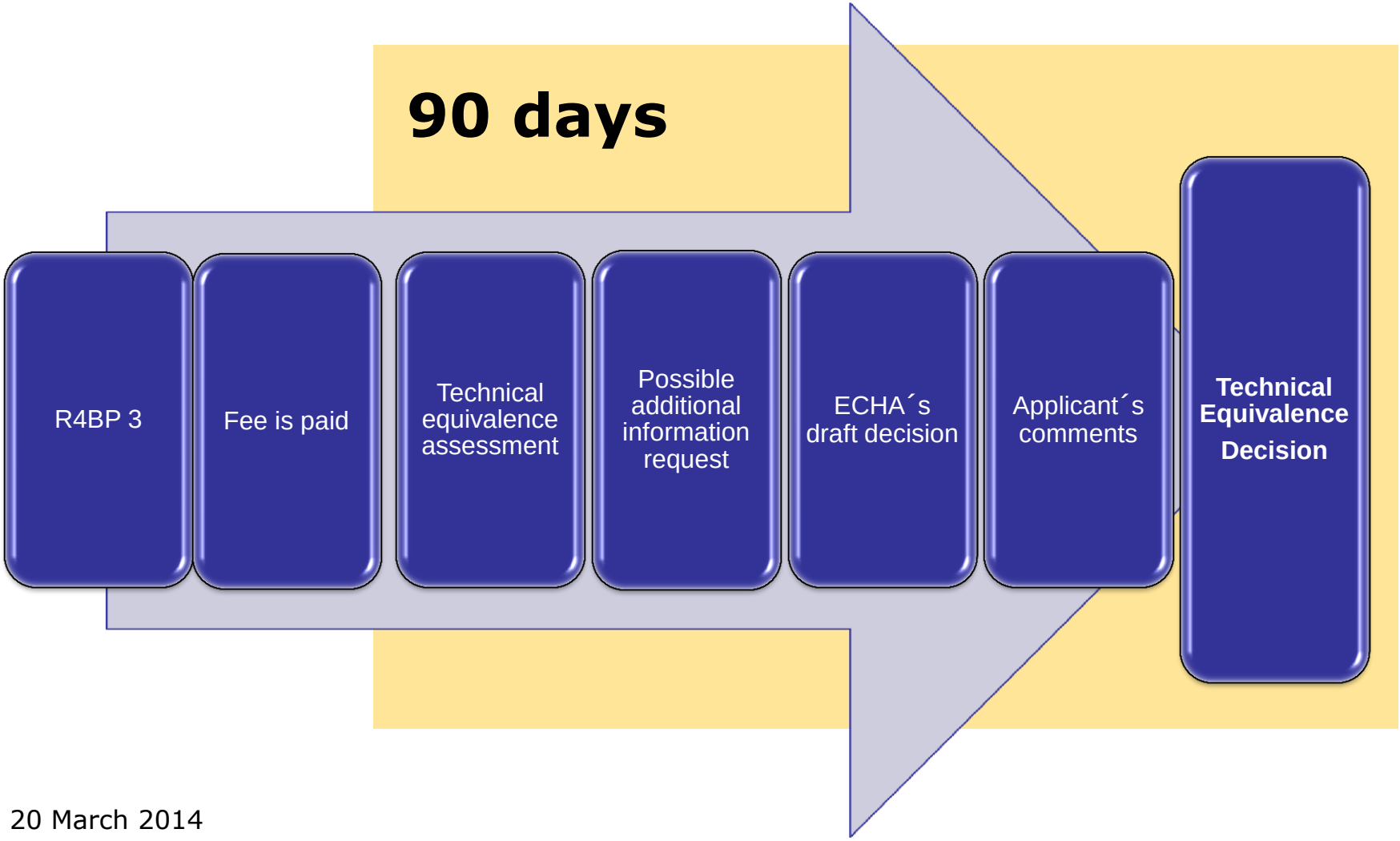
What are the fees?

- Change only in manufacturing location and application is based solely on analytical data ("Tier I" 5 000 euros)
- Change goes beyond the manufacturing location and application is based solely on analytical data ("Tier I" 20 000 euros)
- The application is not based solely on the analytical data ("Tier II" 40 000 euros)

Article 54(4) – Assessment of technical equivalence (cont.)

*"…After **giving the applicant the opportunity to submit comments**, the **Agency shall take a decision within 90 days of receipt of the application** referred to in paragraph 1 and shall communicate it to Member States and to the applicant…"*

Assessment of technical equivalence



Article 54(5)– Assessment of technical equivalence (cont.)

"…Where, in the opinion of the Agency, ***additional information is necessary to carry out the assessment of technical equivalence****, the Agency shall ask the applicant to submit such information within a time limit specified by the Agency. The Agency shall reject the application if the applicant fails to submit the additional information within the specified time limit..". The 90-day period referred to in paragraph 4 shall be suspended form the date of issue of the request unitl the information is receive. The supsension shall not exceeed 180 days except where justified by the nature of the data request or in exceptional circumstances.*

Article 54(5)– Assessment of technical equivalence (cont.)

"…The 90-day period referred to in paragraph 4 shall be suspended from the date of issue of the request until the information is received. The suspension shall not exceed 180 days except where justified by the nature of the data request or in exceptional circumstances…"

Additional information requested?

- Applicants are contacted through R4BP 3 **through adhoc communication**.
- The communication will contain a letter as an attachment with the **information requirements.**
- Simultaneously, a **"re-submission"** task will be generated.

Additional information requested?

How to reply?

- Use **the adhoc communication** to contact ECHA concerning any question on the information request.
- Use the re-submission task **to upload the IUCLID** dossier.

Additional information requested?

- Only one re-submission per information request is allowed.
- If the deadline is missed the application is rejected.
- Technical equivalence applications can only be updated following a request by ECHA.

Article 54(6)– Assessment of technical equivalence (cont.)

"…Where appropriate, the Agency may consult the competent authority of the Member Sate which acted as the evaluating competent authority for the evaluation of the active substance..."

Consultation to Member States

- During the assessment, the Agency may consult the competent authorities
  - Authorities will be contacted through R4BP 3 through ad-hoc communication.
  - The communication will contain a letter as an attachment with the information requirements.
- During the consultation, **the 90-day evaluation is not suspended.**

Article 54(7)–
Assessment of technical equivalence (cont.)

"…An appeal may be brought, in accordance with Article 77, against decissions of the Agency under paragraphs 3, 4, and 5 of this Article..."

Article 54(8)– Assessment of technical equivalence (cont.)

"…The Agency shall draw up technical guidance notes to faciliate the implementation of this Article..."

Guidance

- Guidance on applications for technical equivalence

http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation?panel=guidance_applications_technical_equivalence

- Guidance on information requirements

http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation

- Prepare a dossier-IUCLID

http://iuclid.eu/index.php?fuseaction=home.news&type=public&id=64

- Submit a dossier-R4BP

http://echa.europa.eu/support/dossier-submission-tools/r4bp

Thank you

Virginia.RODRIGUEZUNAMUNO@echa.europa.eu