ECCA
european crop care association

the Data Protection Paradigm shift

Πάντα ρει

Application for authorisation/renewal

substance dossier

product dossier

Πάντα ρει


substance
substance
substance
substance
substance
substance

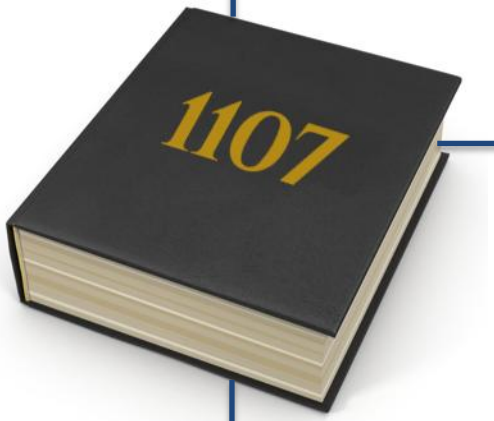

product
product
product
product
product
product

Πάντα ρει


substance
substance
substance
substance
substance
substance
UNPROTECTED


product
product
product
product
product
product
UNPROTECTED

Overview



Chapter II
Section I

Art. 8: Dossiers

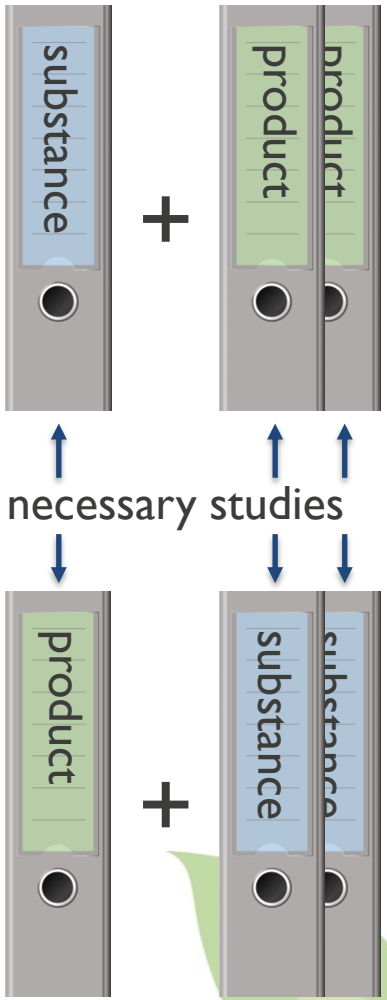
active substance approval

Art. 59, data protection rules

Chapter III
Section I

Art. 33: application

product authorisation



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Substance approval

- *Article 8*
  (Application for approval of an active substance)
- **Dossiers**

8.1 The summary dossier shall include the following: (a) …

b. for each point of the data requirements **for the active substance**, the summaries and results of tests and studies, (…);

c. for each point of the data requirements **for the plant protection product**, the summaries and results of tests and studies, (…), relevant to the assessment of the criteria (…) for one or more plant protection products which are representative of the uses (…); (d)… (e) ...

f. the reasons why the test and study reports submitted are **necessary** …; (g) … (h)…

8.2 The complete dossier shall contain the full text of the individual test and study reports concerning all the information referred to in points (b) and (c) of paragraph 1. …

Overview

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Section I

Art. 8: Dossiers

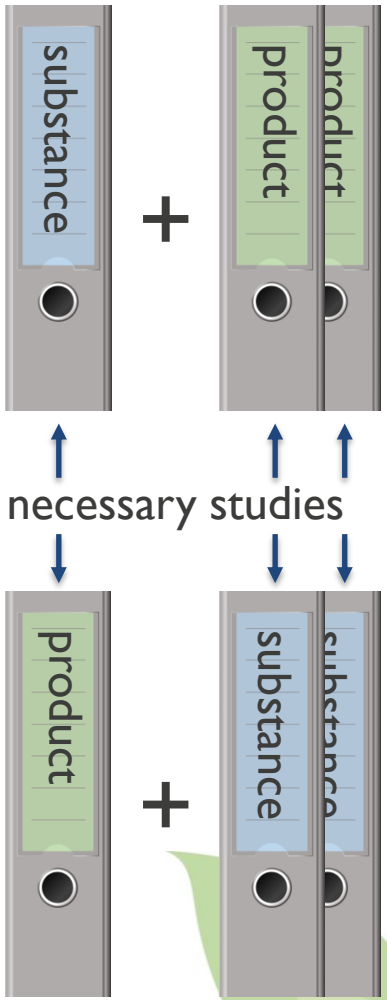
active substance approval

Art. 59, data protection rules

Chapter III
Section I

Art. 33: application

product authorisation



Product authorisation

- *Article 33*
- **Application for authorisation or amendment of an authorisation**

33.3 The application shall be accompanied by the following:

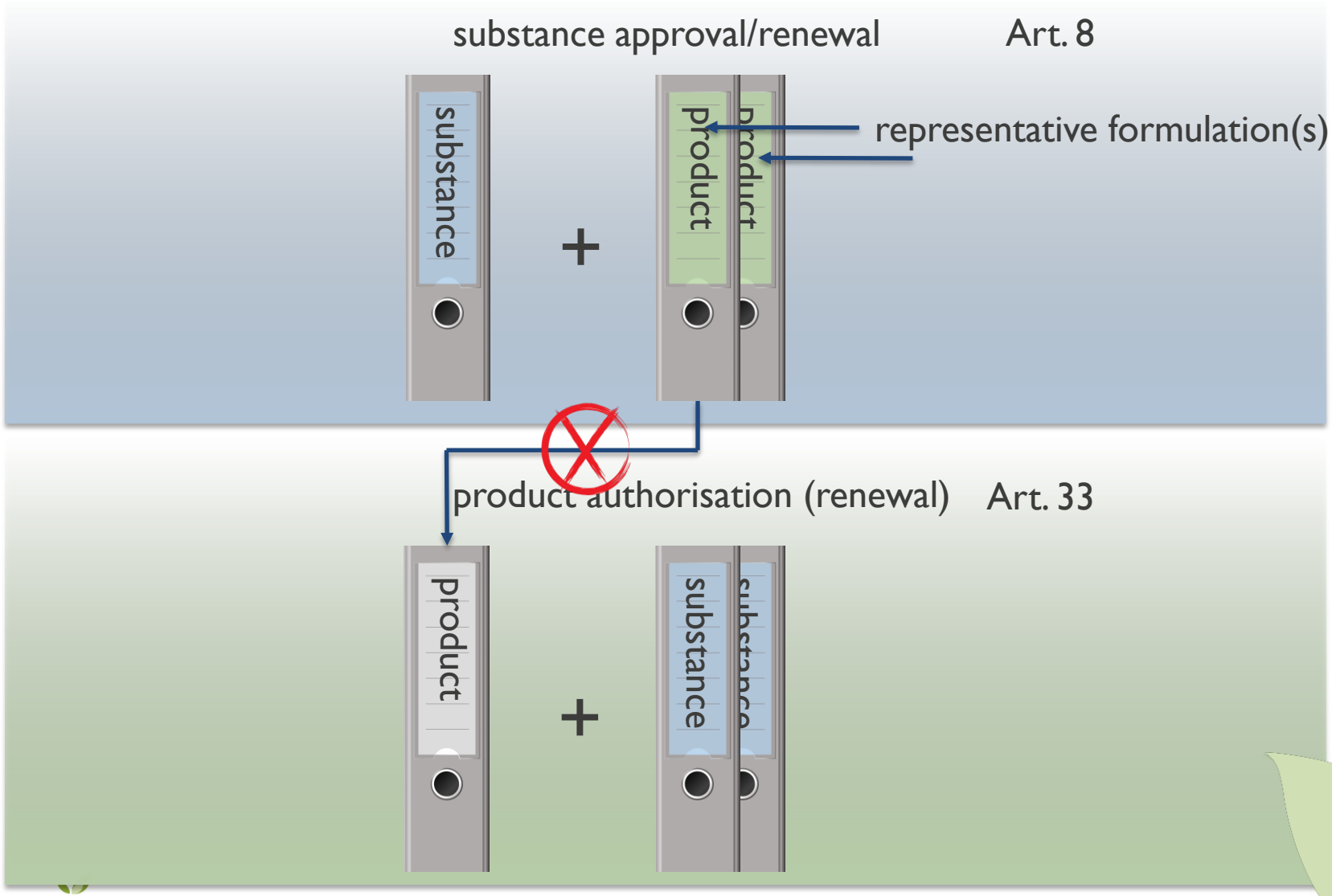
a. for the **plant protection product** concerned, a complete and a summary dossier for each point of the data requirements of the plant protection product;

b. for **each active substance**, safener and synergist contained in the plant protection product, a complete and a summary dossier for each point of the data requirements of the active substance, safener and synergist; c…,

33.3 necessary for the approval

d. the reasons why the test and study reports submitted are **necessary** for first authorisation or for amendments to the conditions of the authorisation ; e…; f…

8.2 + 8.1.f: necessary for the approval
33.3.d: necessary for the authorisation



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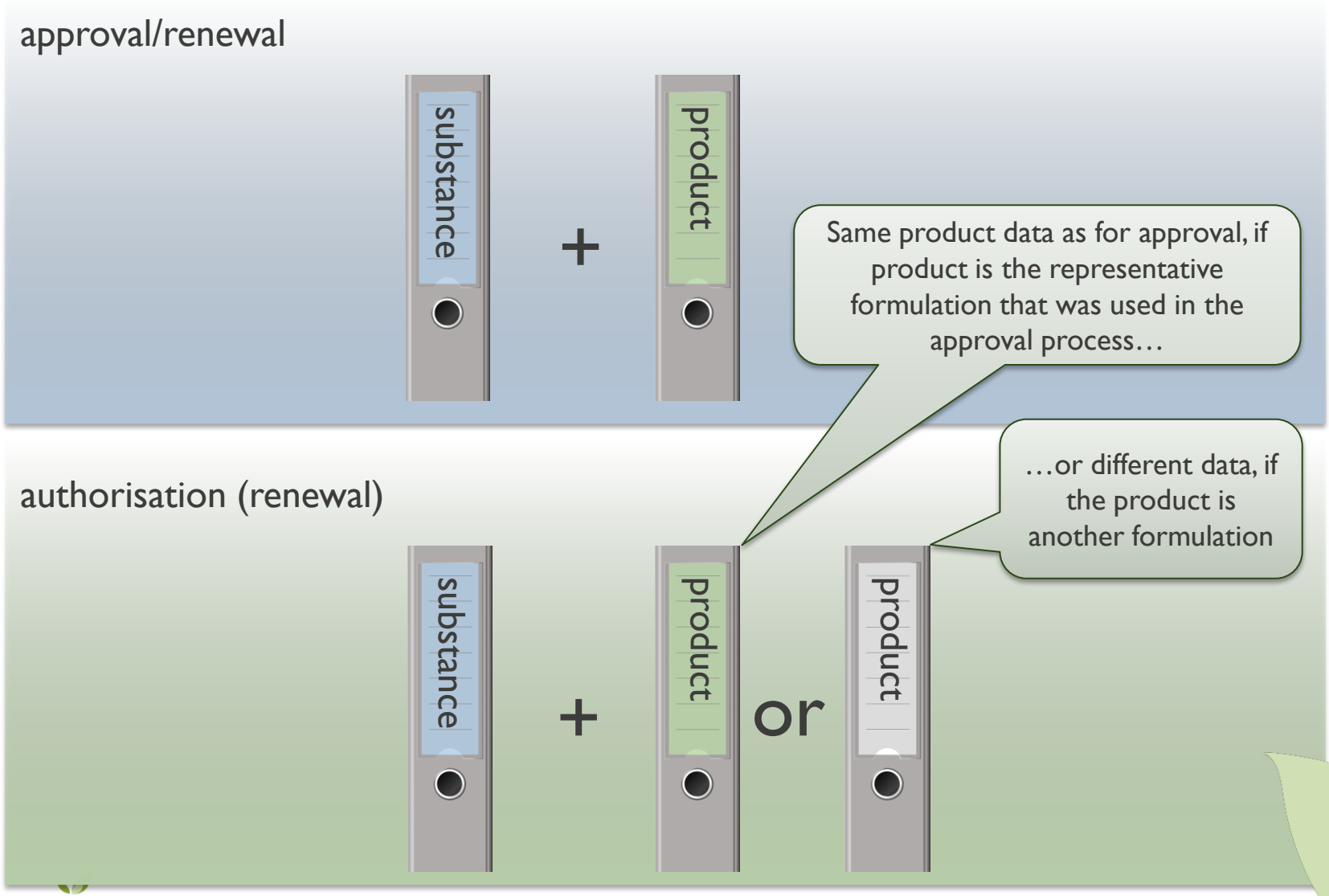
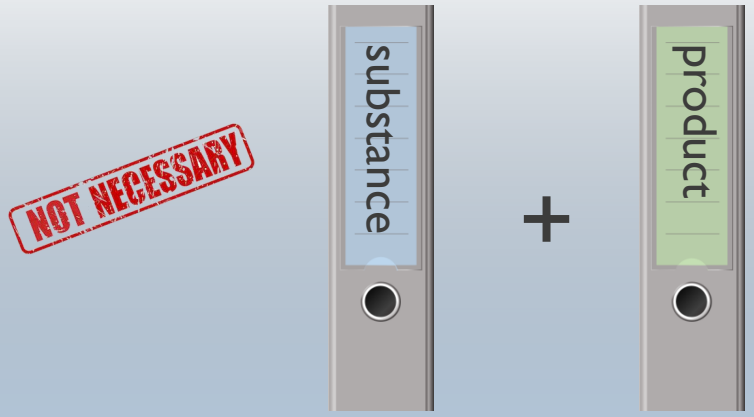
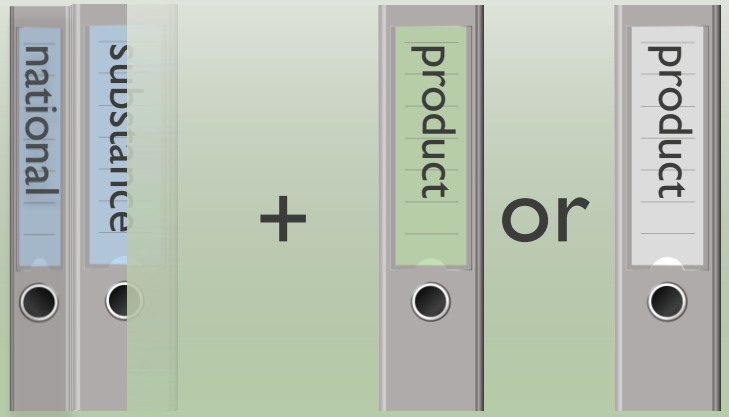


8.2 + 8.1.f: necessary for the approval
33.3.d: necessary for the authorisation

approval/renewal



authorisation (renewal)



- *Article 33*
- **Application for authorisation or amendment of an authorisation**

4. (…)
   The applicant shall at the same time submit the complete list of studies submitted pursuant to **Article 8(2)** and a list of test and study reports for which any claims for data protection pursuant to **Article 59** are requested.

Question: why the list of studies from Art. 8.2 (and not of Art. 33.3), and why the list of protected studies according to Art. 59….?

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- *Article 59*
- **Data Protection**

Maybe because Art. 59 says that data protection applies only to the studies that are listed under Article 8(2)…?

1. Test and study reports shall benefit from data protection under the conditions laid down in this Article.

   The protection shall apply to test and study **reports** concerning the **active substance** (…) and the **plant protection product** as referred to in **Article 8(2)** when they are submitted to a Member State by an applicant for authorisation under this Regulation, (the first applicant), provided that those test and study reports were

   1. **necessary** for the authorisation or an amendment of an authorisation in order to allow the use on another crop; and
   2. (GLP)

…so… protection applies to studies that were necessary in the approval process, and that were necessary for the authorisation, and conducted under GLP

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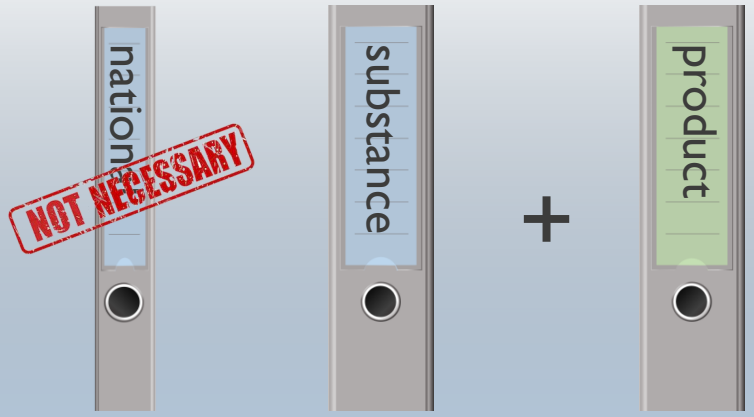
8.2 + 8.1.f: necessary for the approval
33.3.d: necessary for the authorisation

approval/renewal



Art. 59.1
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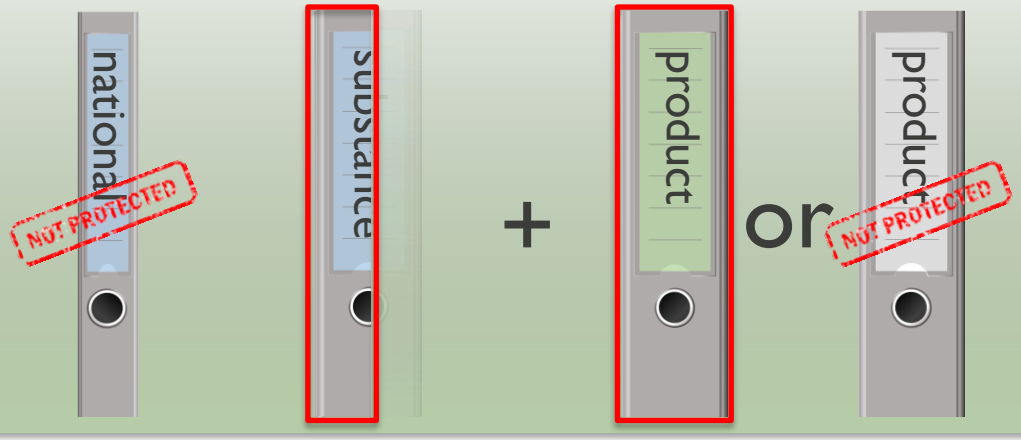
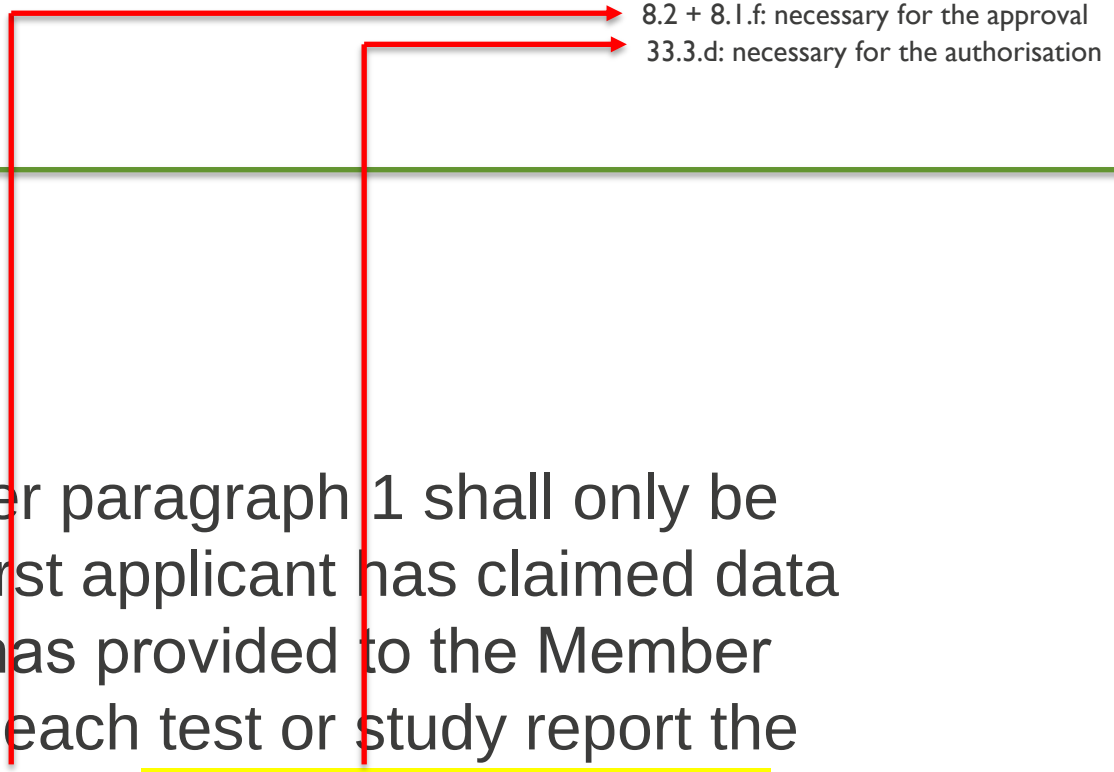
1. **necessary** for the authorisation or an amendment of an authorisation in order to allow the use on another crop

authorisation (renewal)



- *Article 59*
- **Data Protection**

3. Data protection under paragraph 1 shall only be granted where the first applicant has claimed data protection (…) and has provided to the Member State concerned for each test or study report the information referred to in point (f) of Article 8(1) and in point (d) of Article 33(3) as well as confirmation that a period of data protection has never been granted for the test or study report or that any period granted has not expired



- *Article 59*
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accident or intention?

- Commission proposal 12 July 2006:
  - "*A study shall not be protected if it was only necessary for the renewal or review of an authorisation.*"
- After 1st reading in Parliament, COM submitted an "amended proposal" with identical text for Data Protection. Council made compromise proposal (April 2008) and modified the text:
  - "*A study shall also be protected if it was [...] necessary for the renewal or review of an authorisation. […]*
  - "*Data protection […] shall only be granted where the first applicant has […] provided to the Member State concerned for each test or study report the [...] information referred to the Article 8(1)(e) and Article 32(3)(d)*
- In August 2008 Council issued the "common position" with text almost identical to the final text of Reg. 1107/2009

Summary

- Data protection can be granted only for substance and/or product data that were necessary
  - for the approval of the active substance

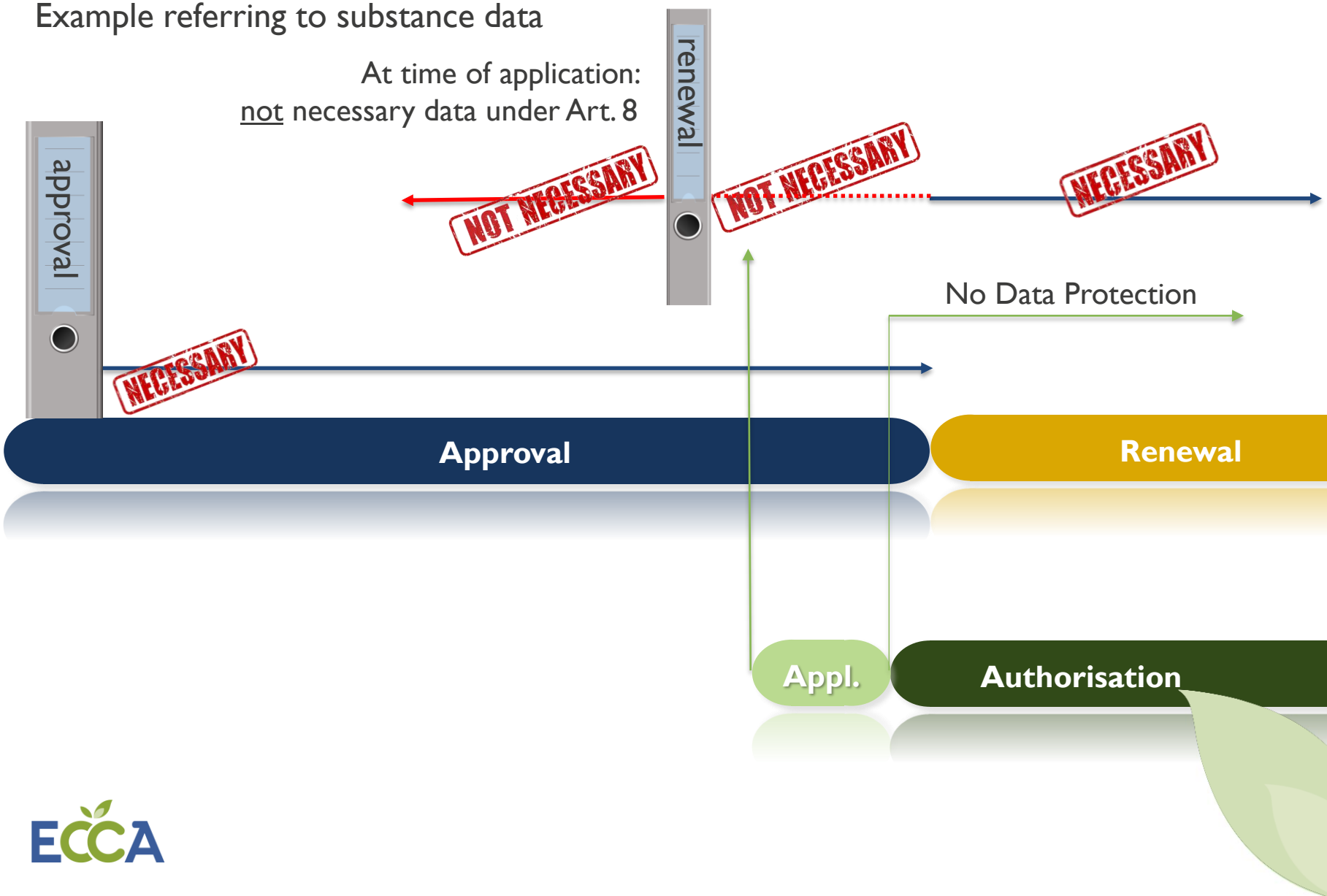
  and
  - for the authorisation of the product

- Not protected are:
  - Product data that were not part of the approval (or renewal) dossier
  - Substance data that were not necessary for the approval (renewal):
    - National data requirements
    - Studies requested under new EU data requirements (after approval)

Summary

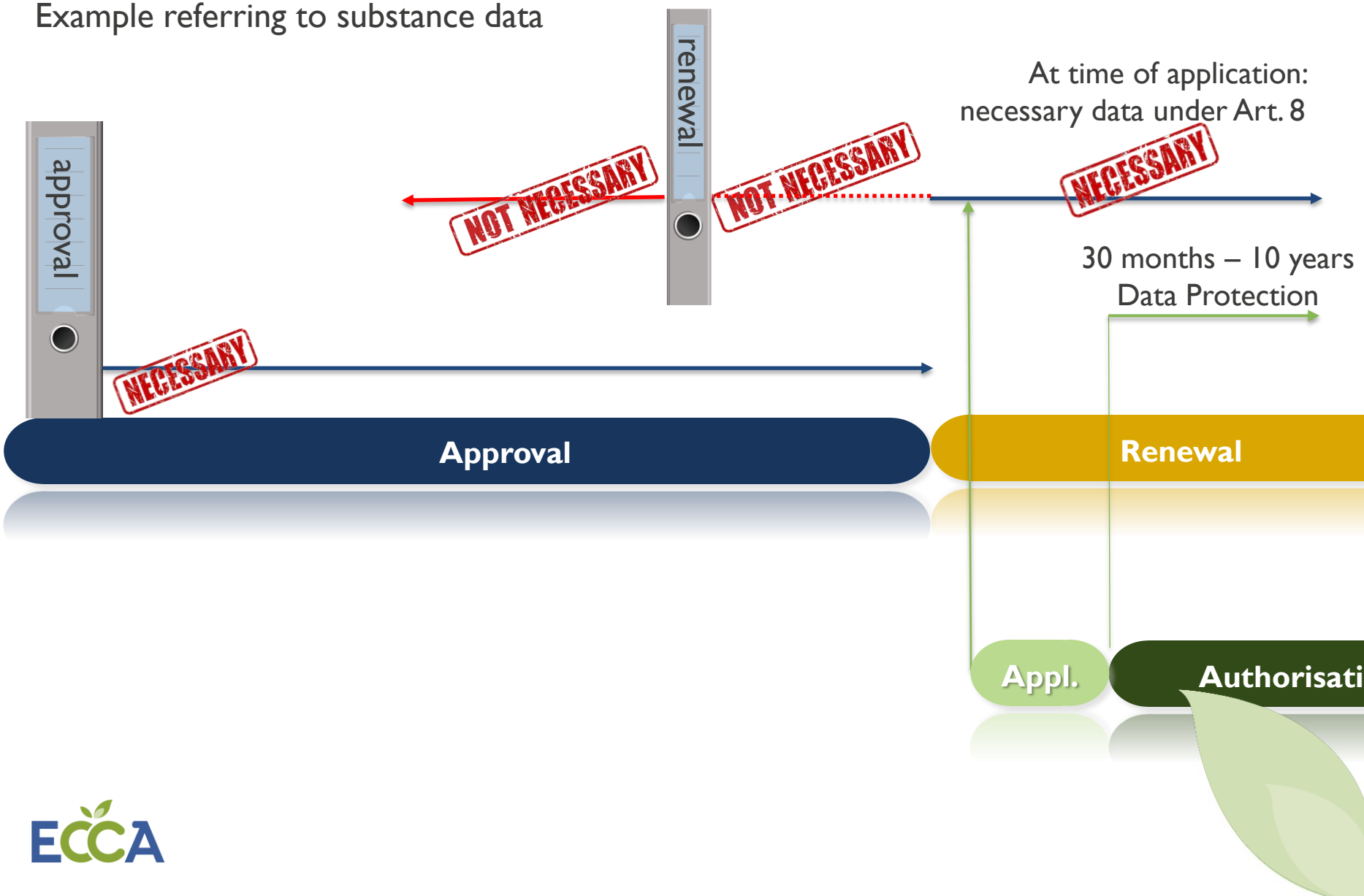
Example referring to substance data

At time of application:
not necessary data under Art. 8



Summary

Example referring to substance data



- Impact on the 10-year trick:
  - Application submitted under previous approval period: therefore at time of submission any submitted new studies were not part of the Art. 8 package of the approval in force, therefore not protected at all.
  - Result: instead of 10 years protection, no protection.
  - Because already used for the “new” product, without a valid data protection claim, not even 30 months protection can be claimed after renewal of the approval…