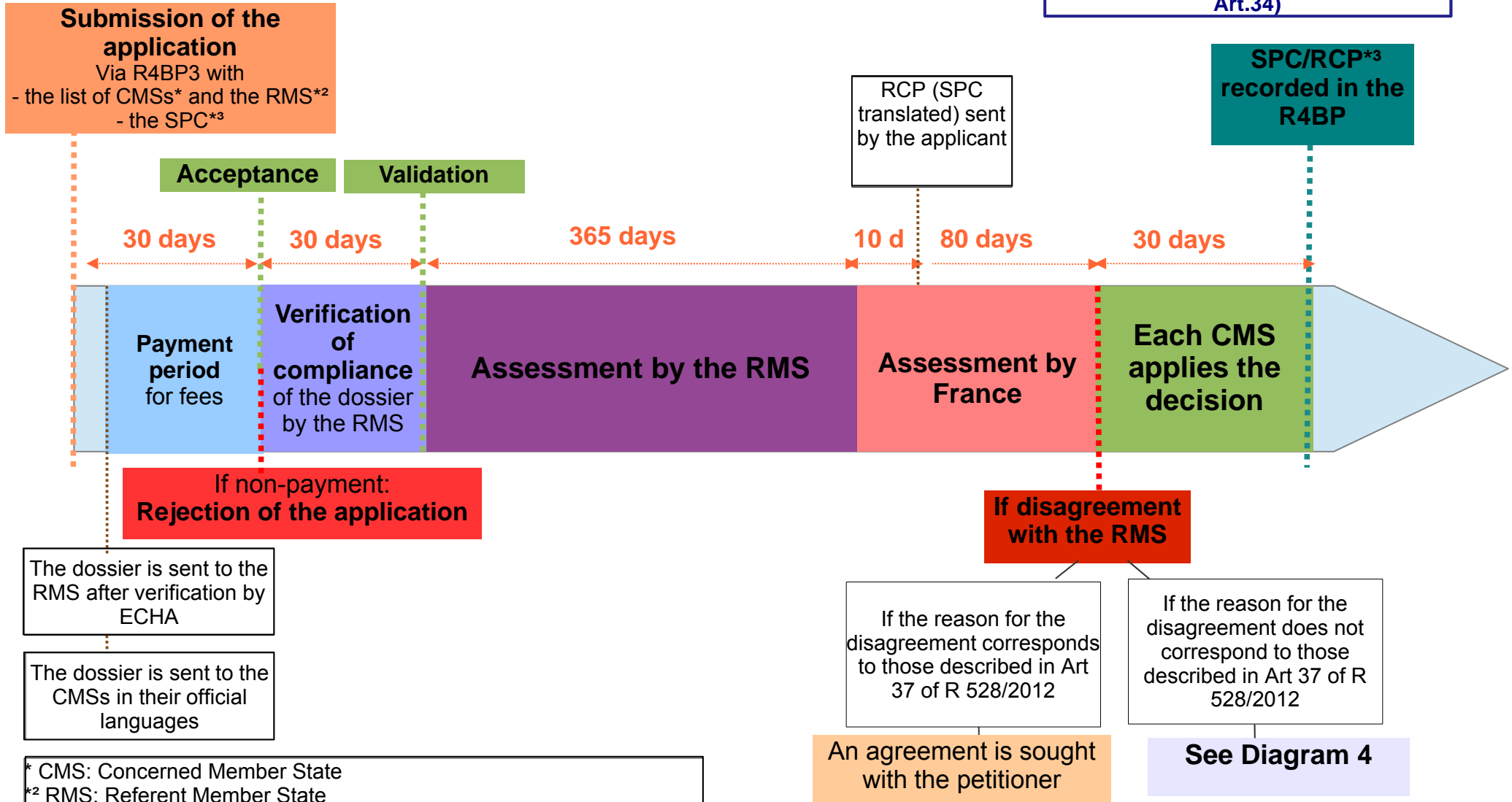


MA Application

with simultaneous mutual recognition procedure
if France is Concerned Member State

In application of the European Regulation (EU) No 528/2012 (Chap. VII Art.34)



The dossier is sent to the RMS after verification by ECHA

The dossier is sent to the CMSs in their official languages

* CMS: Concerned Member State
² RMS: Referent Member State
³ SPC/RCP: Summary of Product Characteristics (in English) / Résumé des Caractéristiques du Produits (in French)

If disagreement with the RMS

If the reason for the disagreement corresponds to those described in Art 37 of R 528/2012

An agreement is sought with the petitioner

If the reason for the disagreement does not correspond to those described in Art 37 of R 528/2012

See Diagram 4

MA Application

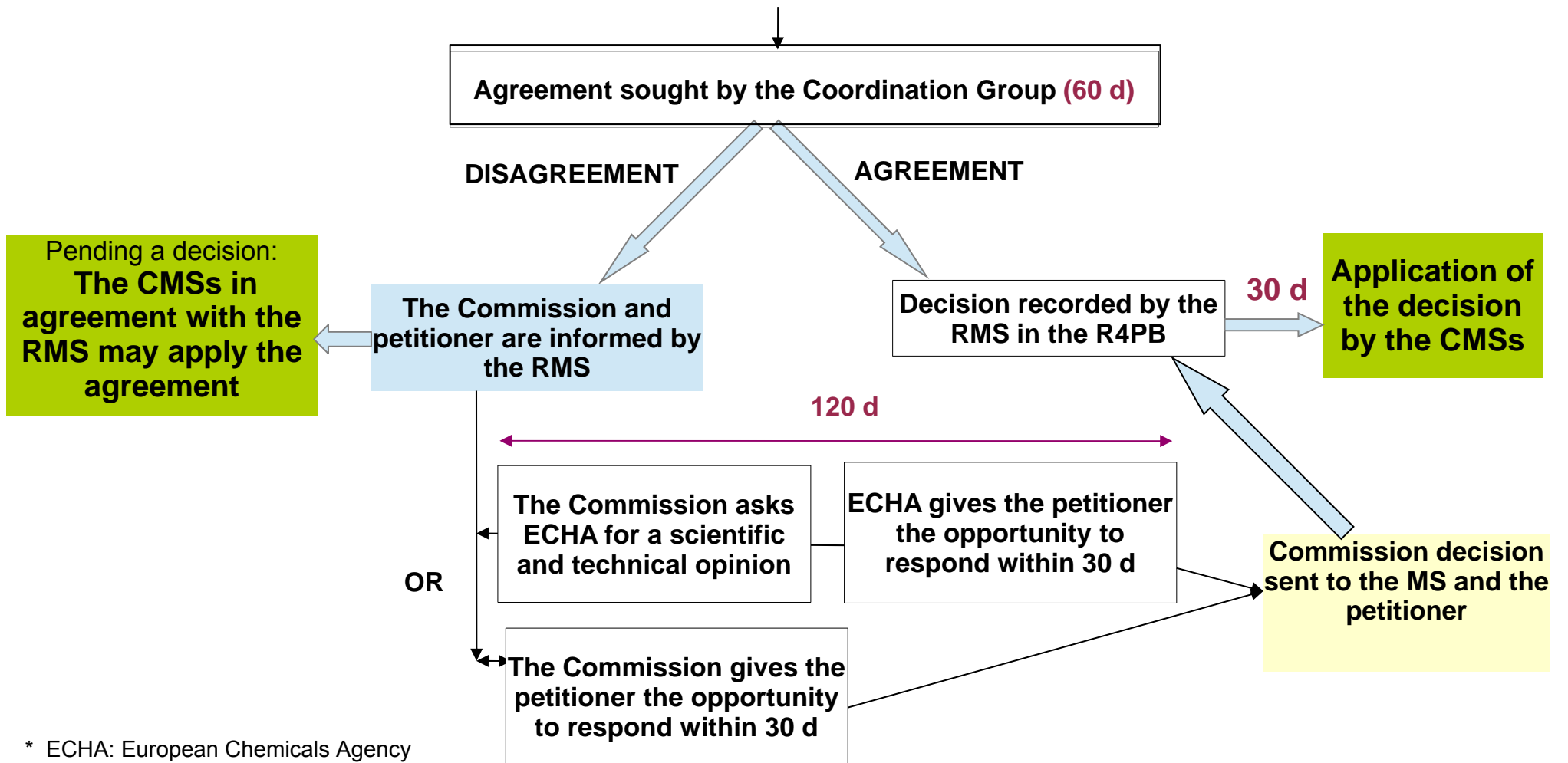
with mutual recognition procedure
if France is Concerned Member State

Diagram 4: In case of disagreement with the RMS

In application of the
European Regulation (EU)
No 528/2012 (Art. 35 and
36)

Drafting of a notification

- by ANSES if the disagreement concerns the assessment
- by the DGRP if the disagreement concerns the decision



* ECHA: European Chemicals Agency