



Article 43 and the generic challenge

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Why is there a challenge?

- Regulation 1107/2009 basic architecture is for a new substance approval, followed by an authorisation
- Majority of regulatory resource is spent on
 - Substance renewal
 - Authorisation renewal
- Regulation not “fit for purpose”

1st approval



renewal



Article 61 challenge

- How to avoid duplicative testing when there's no information on **necessary studies**?
- How to avoid duplicative testing when there's no time to negotiate data sharing?
- How to avoid duplicative testing when there's no penalty for unfair, non-transparent, or discriminatory behaviour of data-owners?
- Do we really want 100+ renewal notifiers for each substance?



Article 61, when? and what?

- Long before application for renewal:
 - Pre-submission meetings
 - Every authorisation holder in the EU becomes notifier?
- “Everybody knows the Data Requirements”
 - It is left to notifiers to decide what’s “necessary”
 - leading to
 - precautionary over-engineering, and/or
 - intentional malicious over-engineering
 - supported by vague, meaningless or false justifications
 - without consequence, and
 - blind copying of the “list” (Art. 60.1)
- Alternative: Data Call-In system:
 - RMS or EFSA does pre-audit, submits proposal for necessary studies for renewal to Commission;
 - Commission together with SCoPAFF decides on necessary studies, publishes in Official Journal the “Data Call-In”:
 - Everybody knows what data are necessary for renewal
 - All interested parties join in a single Task Force



Art. 61 challenge, continued

- Next phase: 1 applicant, or 2, or a Task Force
- other interested parties want to join?:
 - “too late in the process”
 - “only when you buy in to the complete developed package” (80% not “necessary”),
 - “please confirm the specifications of your active substance”
 - “sorry, not interested”, or
 - no reply at all
- Forced to duplicate data, but... what data?
 - RMS accepted list, but does not publish required list of “necessary studies”
 - EFSA changes, almost always, what is considered “necessary”
 - Even at time of renewal, Commission changes once more what EFSA considered “necessary” (see “*Cat. 1 studies*”)



Art. 61 challenge, continued

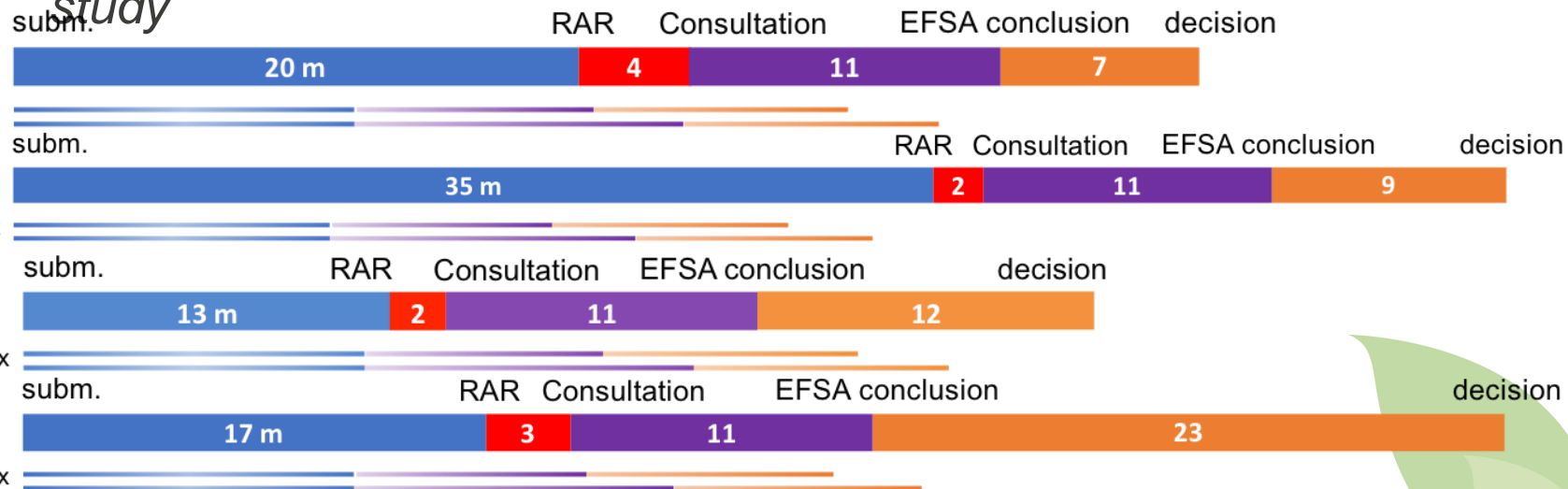
- Only after renewal (plus waiting until publication of Renewal Report):
 - Indication (but no confirmation) of “necessary data”
- How much time left for approaching data owners, to negotiate and conclude data sharing?
 - 3 months
 - realistic?
- Forced duplication of studies,
 - moderated by the competent authorities who did not provide the information to prevent it, and
 - penalised by the competent authorities who assess the renewal dossiers



Art. 61 challenge, continued

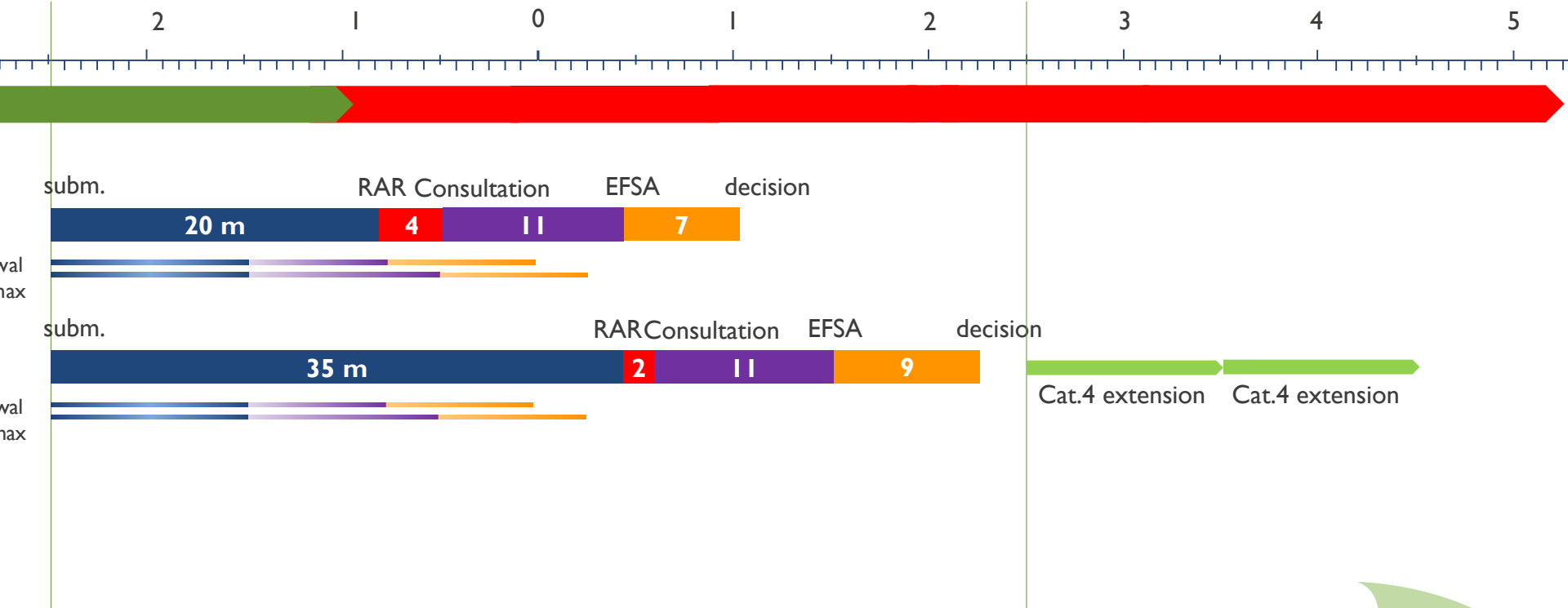
- Cat. 4 studies:

- “Data which are directly related to new guidance 13 in place at the time of submission or to a new/revised endpoint **decided at the time of the renewal of the approval** of the active substance (endpoints as listed in the supporting information to the EFSA conclusions) and for which the time is too short from the **publication of the EFSA conclusion** to produce the requested study”



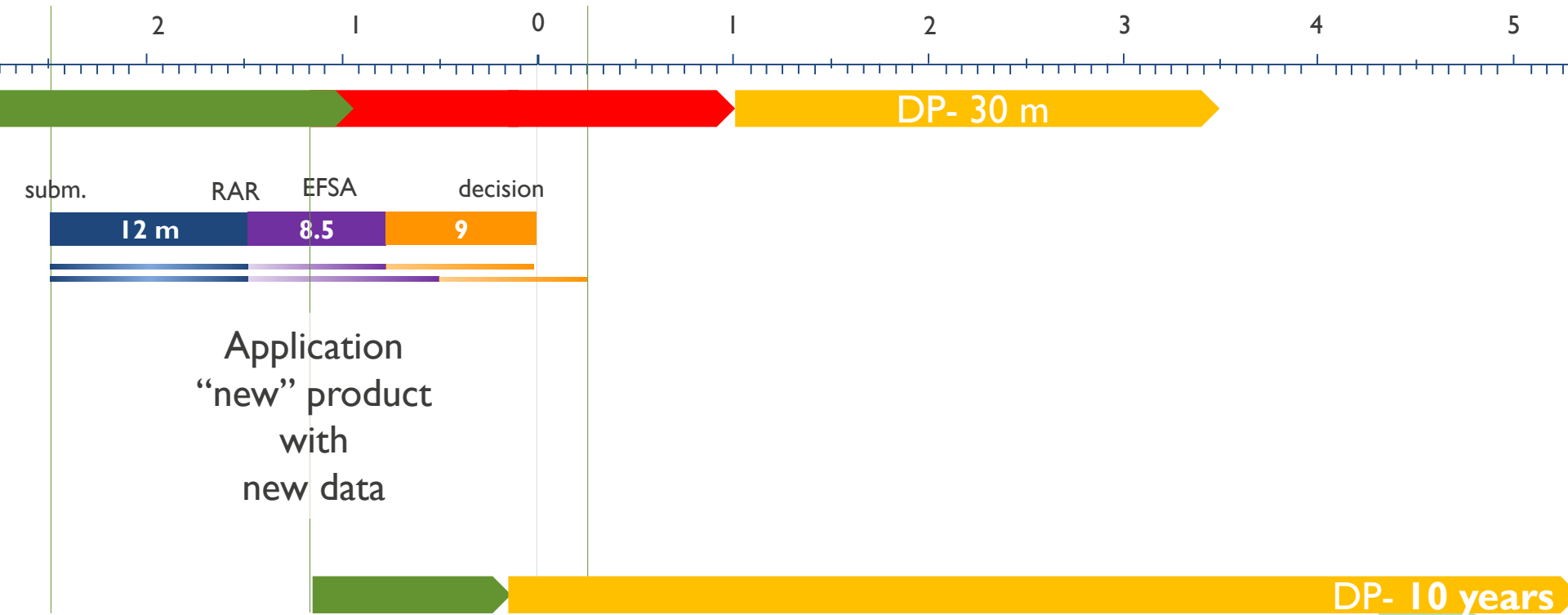
the renewal “lock-out” challenge

Scheduled expiry date



the 10-year trick challenge

Scheduled expiry date



the specification change challenge

substance	renewal regulation	date	old spec (min g/kg)	new spec (min g/kg)	old impurities	new impurities
mepanipyrim	SANTE/2017/10618	draft	960	970	none	Toluene: max. 5 g/kg
copper compounds (Copper hydroxide - Copper oxychloride - Copper oxide - Bordeaux mixture - Tribasic copper sulphate)	SANTE/2018/10505	draft	573 550 820 245 490	573 550 820 245 490	Arsenic max. 0.1 mg/g Cu - Cadmium max. 0.1 mg/g Cu - Lead max 0.5 mg/g Cu	Arsenic max. 0.1 mg/g Cu - Cadmium max. 0.1 mg/g Cu - Lead max. 0.3 mg/g Cu - Nickel max. 1 mg/g Cu - Cobalt max. 3 mg/kg Mercury max. 5 mg/kg - Chromium max. 100 mg/kg - Antimony max. 7 mg/kg
methoxyfenozide	SANTE/2108/10294_rev1	draft	970	970	none	tert-butylhydrazine < 0.001 g/kg; RH-116267 < 2 g/kg
methoxyamid	2018/1264	20/09/2018	940	940	none	Toluene: max. 3 g/kg
carfentazone-ethyl	2018/1061	26/07/2018	900	910	none	none
trifloxystrobin	2018/1060	26/07/2018	960	975	none	AE 1344136 (max. 4 g/kg)
propyzamide	2018/755	23/05/2018	920	920	none	none
silthiofiam	2018/710	14/05/2018	950	980	none	none
zoxamide	2018/692	07/05/2018	950	953	none	none
forchlorfenuron	2018/679	03/05/2018	978	978	none	none
bentazone	2018/660	26/04/2018	960	960	none	1,2-dichloroethane < 3 mg/kg
acetamiprid	2018/113	24/01/2018	990	990	none	none
laminarin	2018/112	24/01/2018	860	860	none	none
glyphosate	2017/2324	12/12/2017	950	950	none	Formaldehyde, less than 1 g/kg N-Nitroso-glyphosate, less than 1
imazamox	2017/1531	07/09/2017	950	950	The impurity cyanide ion (CN-) shall not exceed 5 mg/kg in the technical material.	The impurity cyanide ion (CN-) shall not exceed 5 mg/kg in the technical material.
maleic hydrazide	2017/1506	28/08/2017	940	979	none	Until 1 November 2018, the impurity hydrazine shall not exceed 1 mg/kg in the technical material. From 1 November 2018, the
2,4-DB	2017/1491	21/08/2017	940	940	none	Free phenols (expressed as 2,4-dichlorophenol (2,4-D-DCP)): max. 15 g/kg. Dibenzo-p-dioxins and polychlorinated dibenzofurans
propoxy carbazone	2017/1115	22/06/2017	950	950	none	none
pendimethalin	2017/1114	22/06/2017	900	900	none	1,2-dichloroethane ≤ 1 g/kg Total N-Nitroso compounds: max 100 ppm, of which N-Nitroso-pendimethalin: < 45 ppm.
benzoic acid	2017/1113	22/06/2017	990	990	none	none
flazasulfuron	2017/805	11/05/2017	940	960	none	none
mesosulfuron	2017/755	28/04/2017	930	930	none	none
cyhalofop-butyl	2017/753	28/04/2017	950	950	none	none
mesotrione	2017/725	24/04/2017	920	920	R287431 < 0,0002 % (w/w) in the technical product.	R287431 max 2 mg/kg R287432 max 2 g/kg 1,2-dichloroethane max 1 g/kg
iodosulfuron	2017/407	08/03/2017	910	910	none	none
proprifluron	2017/375	02/03/2017	950	950	none	The impurity 2-(3,3,3-trifluoropropyl)-benzene sulphonamide shall not exceed 10 g/kg in the technical material
thiabendazole	2017/157	30/01/2017	985	985	none	none
ethofumesate	2016/1426	25/08/2016	960	970	none	The following impurities are of toxicological concern and must not exceed the following levels in the technical material: — EMS; ethyl methane sulfonate: maximum of 0,1 mg/kg — iBMS; iso-butyl methane sulfonate: maximum of 0,1 mg/kg
thifen sulfuron-methyl	2016/1424	25/08/2016	960	960	none	none
picochlorfen	2016/1423	25/08/2016	970	980	none	none
acibenzolar-s-methyl	2016/389	17/03/2016	970	970	none	Toluene: max. 5 g/kg
pyrfluorfen-ethyl	2016/182	11/02/2016	956	956	none	none
iprodione	2016/147	04/02/2016	950	950	none	Toluene: not more than 3 g/kg
lambda-cyhalothrin	2016/146	04/02/2016	810	900	none	none
mesosulfuron-methyl	2016/139	02/02/2016	960	967	none	none
esfenvalerate	2015/2047	16/11/2015	830	830	none	The impurity toluene shall not exceed 10 g/kg in the technical material.
2,4-D	2015/2033	13/11/2015	960	960	none	Free phenols (expressed as 2,4-D-DCP): not more than 3 g/kg. Sum of dioxins and furans (WHO-TCDD TEQ) (2): not more than 0,01 mg/kg.
florasulam	2015/1397	14/08/2015	970	970	none	Impurity: 2,6-DFA, not more than 2 g/kg
fenhexamid	2015/1201	22/07/2015	950	975	none	The following relevant impurity must not exceed a certain threshold in the technical material: — toluene: max. 1 g/kg, — 4-amino-2,3-dichlorophenol: max. 3 g/kg.
feric phosphate	2015/1166	15/07/2015	990	703	none	none
sulfosulfuron	2015/1154	14/07/2015	980	980	none	Phenol: < 2 g/kg
pyridate	2015/1115	09/07/2015	900	900	none	none
kresoxim-methyl	2011/810	11/08/2011	910	910	none	Methanol: max. 5 g/kg Methyl chloride: max. 1 g/kg Toluene: max. 1 g/kg
fluroxypyr	2011/736	26/07/2011	950	950	none	none
imazalil	2011/705	20/07/2011	950	950	none	none
azoxystrobin	2011/703	20/07/2011	930	930	Z isomer maximum 25 g/kg)	Toluene maximum content 2 g/kg Z-isomer maximum content 25 g/kg
prohexadione-calcium	2011/702	20/07/2011	890	890	none	none
azimsulfuron-methyl	2010/54	20/08/2010	980	980	none	maximum level of the impurity phenol 2 g/kg



the specification change challenge

- Minimum purity change:
 - No reason, other than the notifier's new manufacturing specs
- Max impurities:
 - Based on hazard?
 - No justification
 - Max. levels depend on notifier's specs
 - 1,2-dichloroethane:
 - Pendimethalin: <1,000 mg/kg
 - Mesotrione: <1,000 mg/kg
 - Bentazone: <3 mg/kg
 - toluene:
 - 1, 1, 2, 3, 3, 5, 10 g/kg



**Thank you
for your
attention**

