Health and Safety
Executive

HSE

An introduction to Article 43

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What Article 43 says:

Applicants must:

- Submit product renewal application within 3 months of a.s. renewal
- Address new data requirements & criteria
- Provide evidence that new data are necessary
- Provide info to show product complies with a.s. renewal regulation

Renewal, withdrawal and amendment[1]

Article 43

Renewal of authorisation

1. An authorisation shall be renewed upon application by the authorisation holder, provided that the requirements referred to in Article 29 are still met.

2. Within 3 months from the renewal of the approval of an active substance, safener or synergist contained in the plant protection product, the applicant shall submit the following information:

(a) a copy of the authorisation of the plant protection product;

(b) any new information required as a result of amendments in data requirements or criteria;

(c) evidence that the new data submitted are the result of data requirements or criteria which were not in force when the authorisation of the plant protection product was granted or necessary to amend the conditions of approval;

(d) any information required to demonstrate that the plant protection product meets the requirements set out in the Regulation on the renewal of the approval of the active substance, safener or synergist contained therein;

(e) a report on the monitoring information, where the authorisation was subject to monitoring.

What Article 43 says:

3. Member States shall check compliance of all plant protection products containing the active substance, safener or synergist concerned with any conditions and restrictions provided for in the Regulation renewing the approval under Article 20.

The Member State referred to in Article 35 within each zone shall coordinate the compliance check and assessment of the information submitted for all Member States within that zone.

4. Guidelines on the organisation of compliance checks may be established in accordance with the advisory procedure referred to in Article 79(2).

5. Member States shall decide on the renewal of the authorisation of a plant protection product at the latest 12 months after the renewal of the approval of the active substance, safener or synergist contained therein.

6. Where, for reasons beyond the control of the holder of the authorisation, no decision is taken on the renewal of the authorisation before its expiry, the Member State in question shall extend the authorisation for the period necessary to complete the examination and adopt a decision on the renewal.

MSs must:

- Work zonally
- Check compliance with approval conditions
- Decide on renewal within 12 months of renewal of approval
- If decision delayed can extend existing authorisations

Why only 3 months?

- Products already authorised to UPs
- Only need to address changes resulting from the renewal of the active substance

… however

- EFSA now peer reviewing active substances
- New risk assessment guidance in several areas
- New data requirements will apply

Re-registration Vs Renewal

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Re-registration 91/414

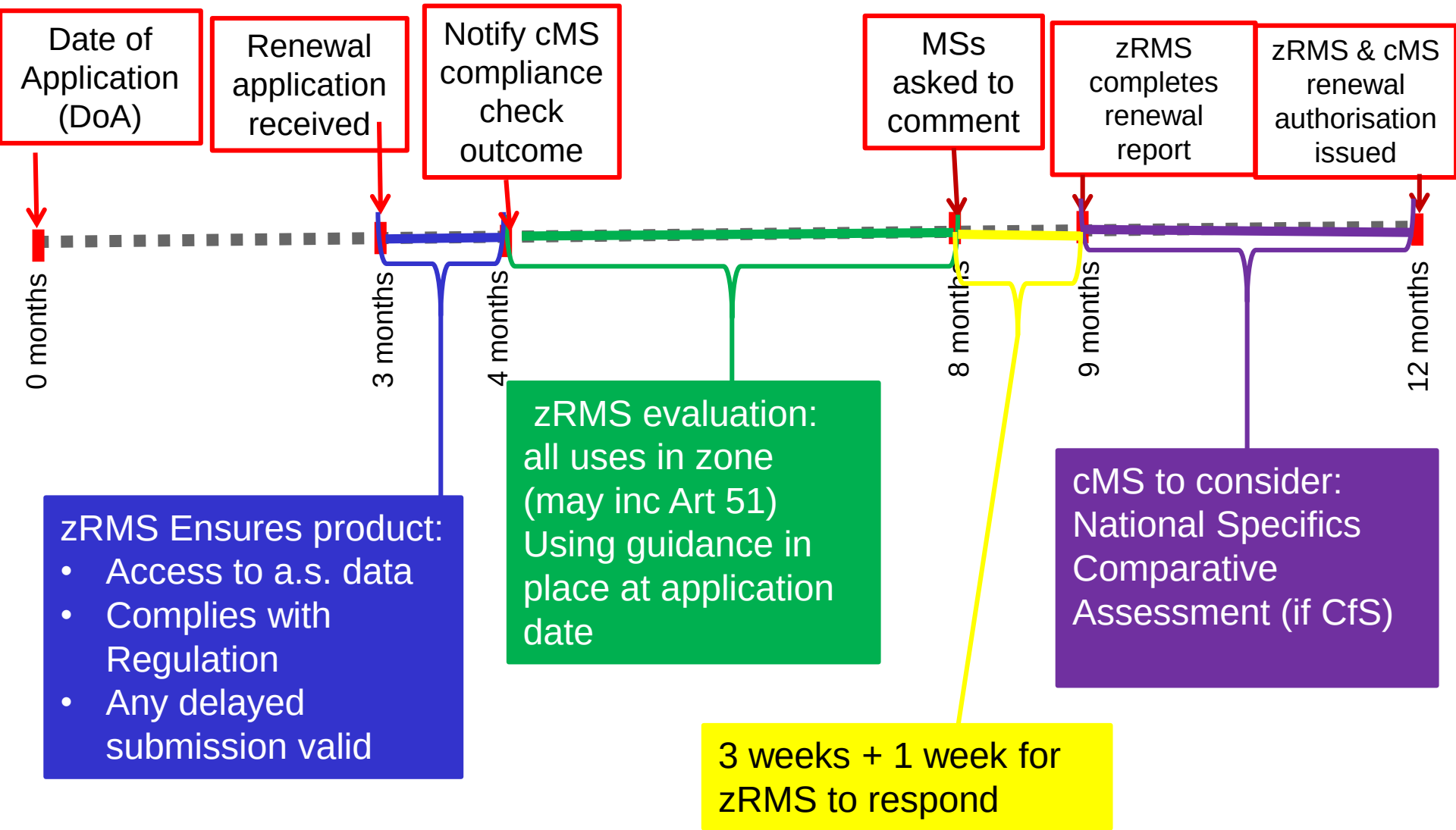
- Directive – no detailed rules
- 2 years for submission
- 2 years for evaluation
- New assessments to UPs
- Re-registration with last active inclusion

Vs

Renewal 1107/2009

- Regulation – timelines apply directly
- 3 months submission
- 9 months for decisions
- Updated assessments
- Renewal with every approval

Product Renewal Timeline (after a.s. approval)



List of Changed Endpoints

EFSA will highlight where endpoints have changed in the LOEP for AIR 3 actives.

A.S. RMS will do this work for upcoming AIR 2 actives.

Available via public area of CIRCABC (or direct from RMS).

TOX		
Classification proposed	R43	None
ADI	0.2 mg/kg bw/day	0.2 mg/kg bw per day 1-year, dog
AOEL	0.3 mg/kg bw/d	0.2 mg/kg bw per day 1-year, dog
ARfD	Not required	Not required
Dermal abs.	18% for dilutions, 2 % for concentrate (from in vivo rat study).	Concentrate: 0.2 % Spray dilution (5 g/L): 1 % Spray dilution (0.375 g/L): 8 % In vitro absorption through human skin
RESIDUES		
Plants Residues Def.	Fenhexamid	Fenhexamid
Animals Residues Def.	Not required	Not required
Following crops	Not studied (due to rapid degradation of fenhexamid in soil)	Very low to low persistence (DT50 of fenhexamid: 0.08 – 1.07 d). No rotational crop field trials are required.
MRL	Highest 5 mg/kg (cherry)	Highest 4 mg/kg (table grapes)

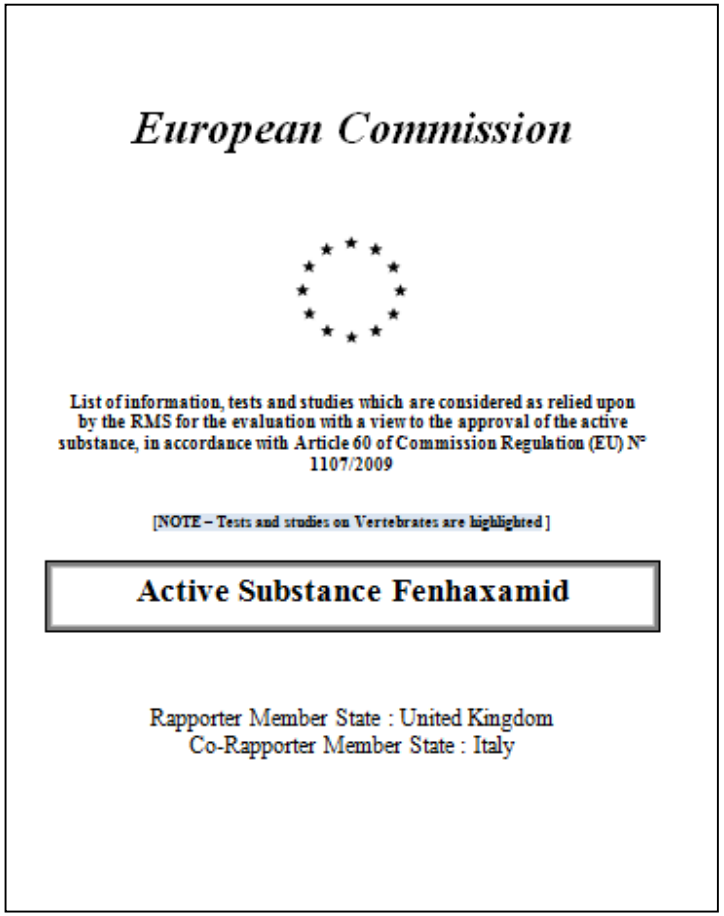
FENHEXAMID - Fungicide	**First Annex I**	**Renewal**
E-FATE		
Residue definition	Parent only in all compartments	Soil and sediment: Fenhexamid Surface water: Fenhexamid and M15 Groundwater: Fenhexamid and M24
DT50 soil	PECsoil DT50 = 1 d (SFO)	PECsoil DT50/90 = 1.07/10 d (FOMC) PECsw/gw = 0.43 d (SFO)
DT50 water	PECsw DT50 = 7 d (SFO dissT50)	PECsw DT50 = 10.9 d

List of Studies Relied upon for Active Substance Renewal

Active Substance RMS should ensure that this is completed and available by the time the EFSA conclusion is published.

Available publically via CIRCABC & direct from zRMS.

Delays in availability of this document create huge difficulty for off-patent (generic) manufacturers.



European Commission

List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the approval of the active substance, in accordance with Article 60 of Commission Regulation (EU) N° 1107/2009

[NOTE – Tests and studies on Vertebrates are highlighted]

Active Substance Fenhaxamid

Rapporter Member State : United Kingdom
Co-Rapporter Member State : Italy

Noting at Standing Committee

- Renewal regulation sets DoA and the new active expiry date
- Renewal date will be set ASAP after voting (in line with Art 17)
- MS will (where necessary) adjust product expiry dates
- RMS should ensure list of critical data is available

Pre-submission meetings

- Not essential (in UK) but encouraged if CAT 4 proposed (discussed in next slide)
- Can discuss a portfolio of products in same meeting
- Useful to help plan strategy
- Agenda determined by applicant
- £5,200 fee, applicant to take minutes/notes

Category 4 Delayed Renewal

Data necessary due to new endpoints, but insufficient time, from EFSA conclusion, to produce new study.

Applicant must justify why CAT 4 applies

If zRMS agrees:

- Sets submission date (3 months after final study complete)
- Notifies cMS to extend authorisations

No agreed upper limit on delay – a 2 year delayed submission is acceptable **if it can be justified**

Can be problems if >1 zRMSs with different opinions

Assessment report - dRR

GD requires - *A complete dRR in which changes to risk assessment are highlighted*.

AIM: A 'stand alone' document must be supplied by the applicant showing how the product is supported in all areas (i.e. complete RR which could be used for MR) **BUT…**

…only need new assessment where data requirements, endpoints or guidance changed.

Where previous assessment remains valid, we include previous MS assessment in dRR (identify MS & date)

Assessment Report - dRR (2)

- Expectation formulation studies remain valid (e.g. Phys chem props/ tox / ecotox). Sections may need updating for new relevant impurities / CLP
- Methods – New studies may necessitate new methods assessments (e.g. if new relevant impurity)
- If no GAP change minimal efficacy (no substantive changes to efficacy data requirements – Unless there is a change in GAP will only need to update resistance section)

dRR (3) - Mixed a.s. products

- Application required after **each** a.s. renewal but dossier submission can be delayed if renewal dates <12m apart at any point.
- dRR should present assessment relating to the active(s) which has triggered renewal
- If dRR delayed as expiry dates <12 months apart;

- Use guidance in place at 2nd a.s. submission applies

- Combined toxicity is not yet harmonised. Combined assessment must be presented at each submission but it's up to the zRMS whether or not to assess. In the UK we will only consider at the renewal of last active in the product.

Submitting to UK

At 3 month deadline submit for every compliant* product:

- Letter / overview
- Copy of authorisation, application form (CRD-R)
- Demonstration of active substance data access
- Declaration that product & source(s)* comply with restrictions / conditions in renewal regulation (in CRD-R)
- List of all uses supported in the zone (ideally including article 51 minor uses to be supported)

*In principle non compliant uses cannot be renewed (The UK is permitting some flexibility here). If a new technical equivalence assessment required this must be submitted under a separate application.

Submitting to UK (2)

- Statement that GAP in each MS is unchanged from previously authorised.
- New data (plus Cat 4 justification where relevant).
- Evidence/justification that new data provided (or to be submitted if Cat 4 applies) are necessary.

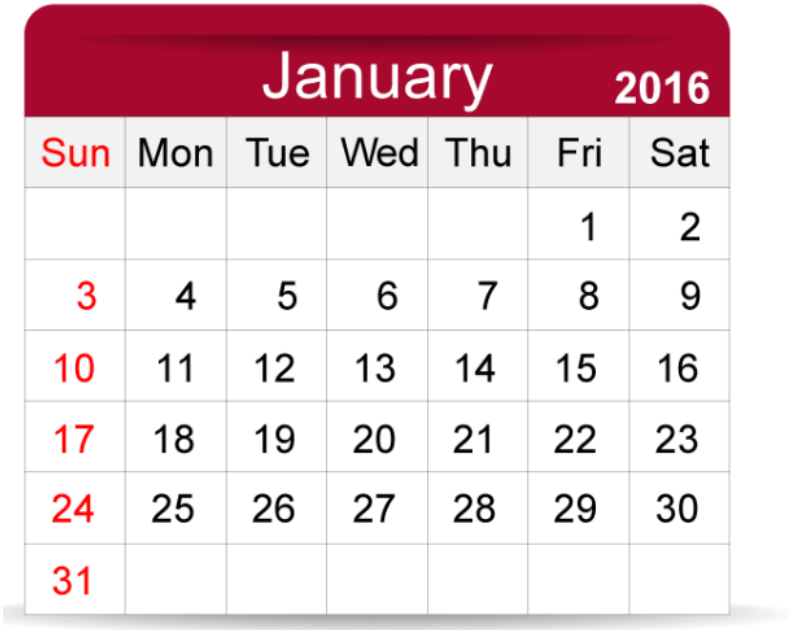
Unless delayed submission is justified, also need::

- Complete dRR highlighting new data & risk assessments.
  (Including updated assessment of UK national requirements)
- draft label
- If the product contains a Candidate for Substitution, a comparative assessment must be supplied.

zRMS/ cMS overview

zRMS, ideally within 1 month:

- Check active data access (main check done by a.s. RMS)
- Check compliance (product & uses) with renewal regulation
- Consider CAT 4 justifications (liaise where >1 zRMS for a.s.)
- Agree (or not) authorisation extensions & advise cMSs



January 2016

Sun	Mon	Tue	Wed	Thu	Fri	Sat
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

zRMS/ cMS overview

zRMS, within 6 months (if not delayed renewal)

- Conduct risk assessment.

  No possibility to stop the clock so very limited in terms of accepting additional information. In principle requests for minor clarification are permissible but there should be no new data.
- Circulate for commenting (3 weeks).
- Issue national authorisation.
- Advise cMS of outcome and provide final Reg Report.

cMS, within 3 months of zRMS conclusion:

- should recognise zRMS conclusions, consider national specifics, issue national authorisation.

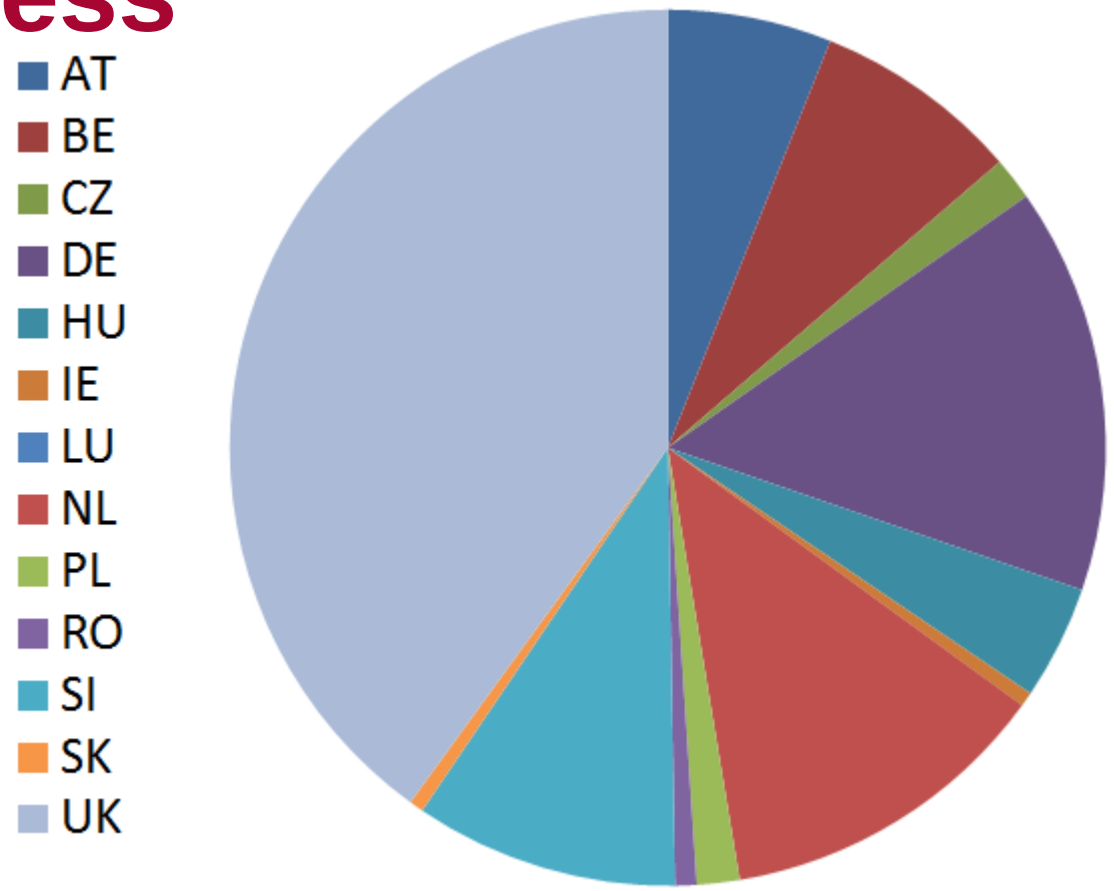
Summary

- UK planning workload as best we can
- Submission required 3 months after every active re-approval, for each active in a product
- Delayed renewal may be justified
- UK aiming to streamline internal process and focus on essential only
- Questions remain: UK working with other MS and COM to resolve

AIR 2 Progress

Distribution of renewal in CZ

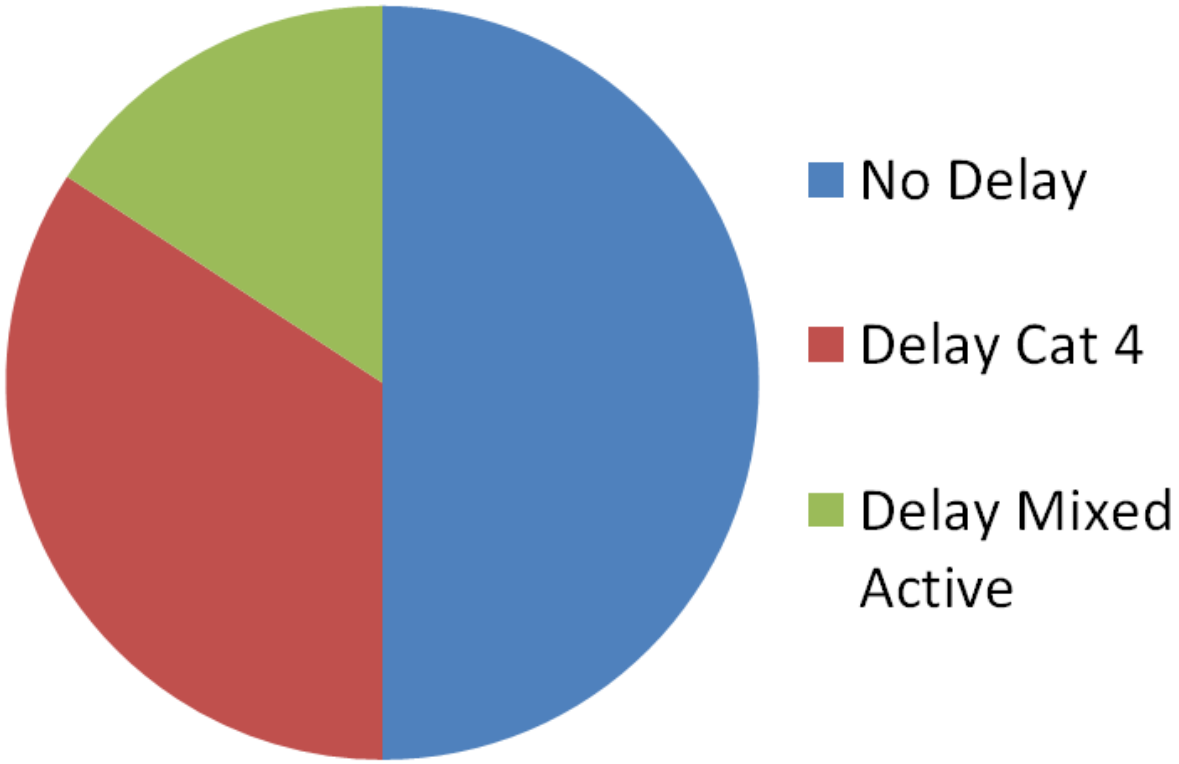
Many MSs already at capacity – In theory renewal could require 40% increase in workload.



Application types received so far (UK)

Broadly as predicted

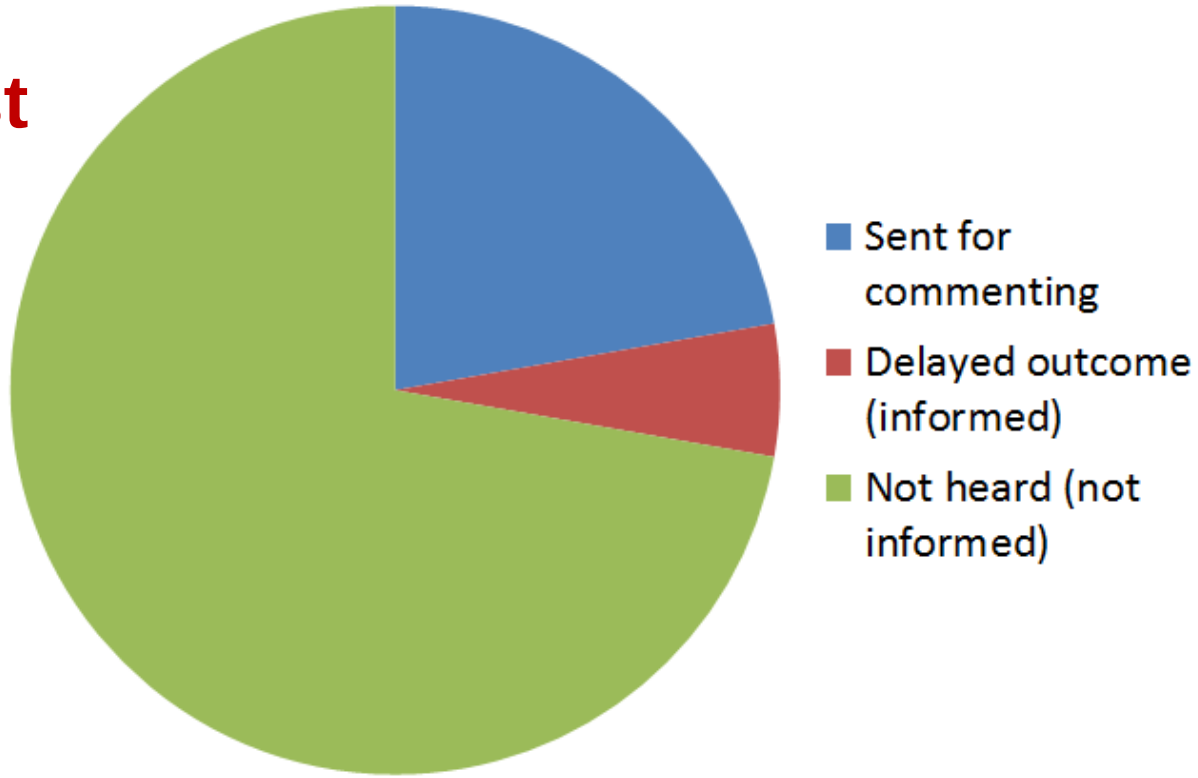
Cat 4 delay significantly more resource intensive



CZ – First Tranche – Progress

By now zRMS assessment of first tranche should be complete

Data is >2 weeks old but MSs are struggling to meet timelines



Conclusions

- What was originally envisaged to be a simple job now more complex
- Timelines set out in Regulation – difficult now for some products given changes
- Legislative requirements only in Regulation – Guidance developed to flesh out the detail of the procedures

Thank you

Any Questions?

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