Zonal approach to registration & its consequences

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Regulation 1107/2009 & Zonal registration

- Since 14 June 2011, industry has the obligation to submit a zonal applications for :
  - New product
  - Label extension
  - Change of composition
- Zonal submissions are strongly recommended for EU Step 2 dossiers (post-Annex I national re-registrations)
- Dossiers submitted prior to June 14, 2011 under 91/414/EEC directive will be evaluated at national level:
  - In most countries there will be no time constraints for the authorities;
  - Priority is clearly given to zonal dossier as evaluation and registration have to be performed under strict timelines

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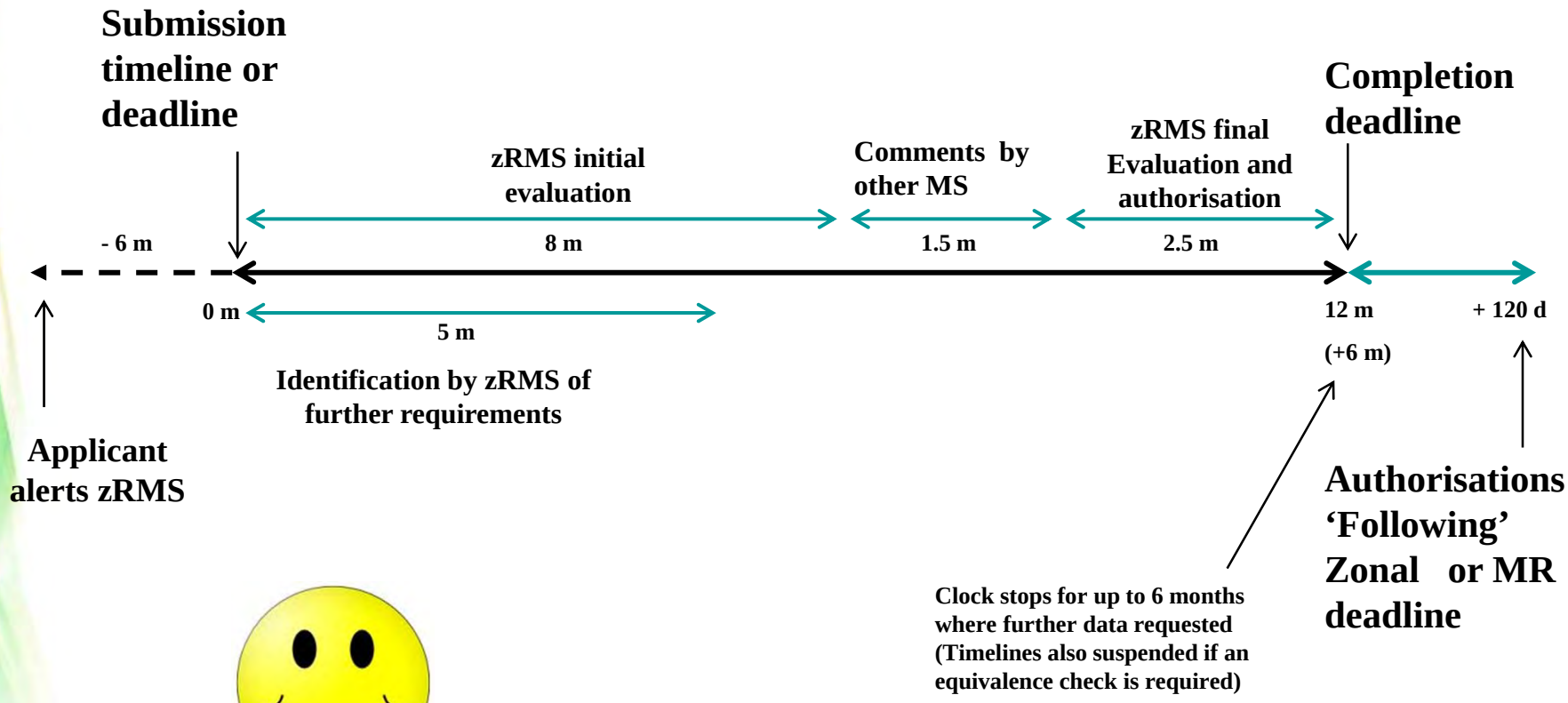
Time frame for product authorisation



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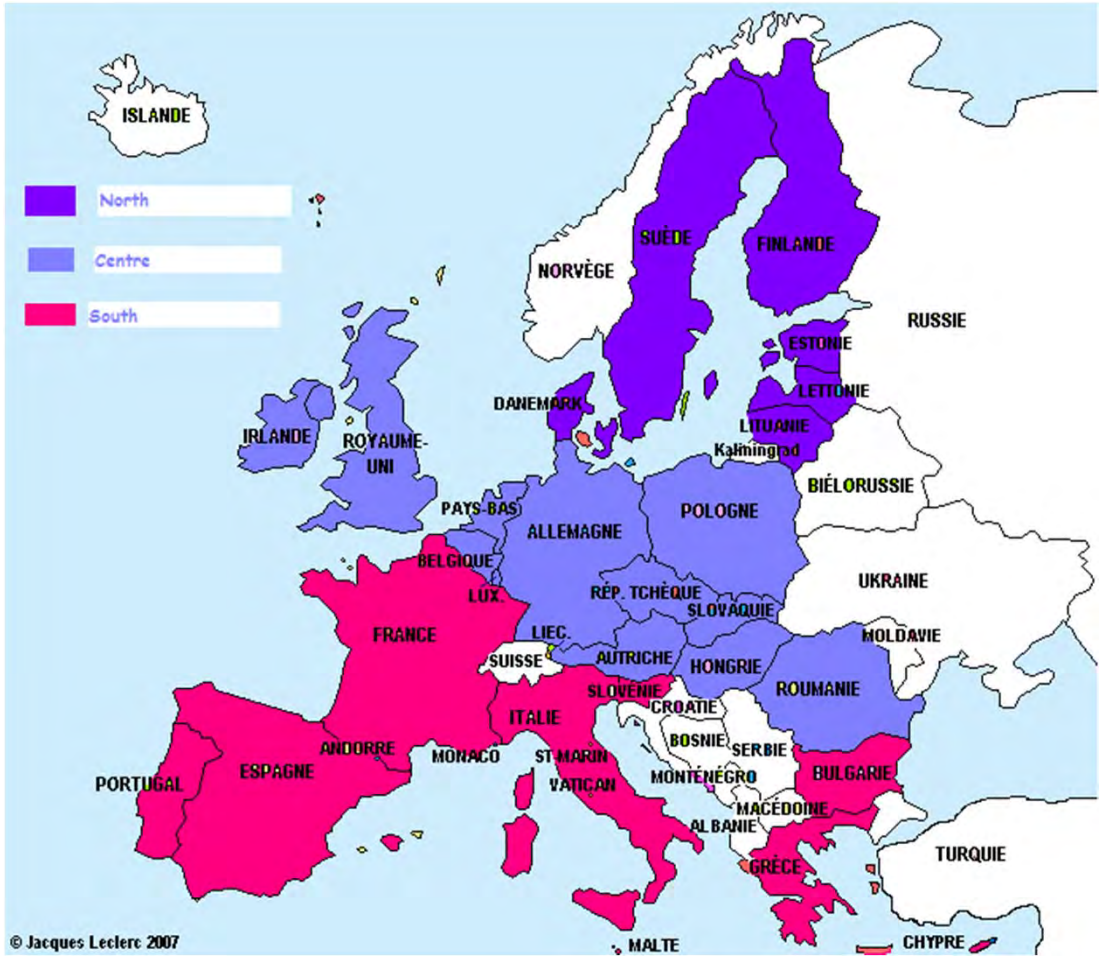
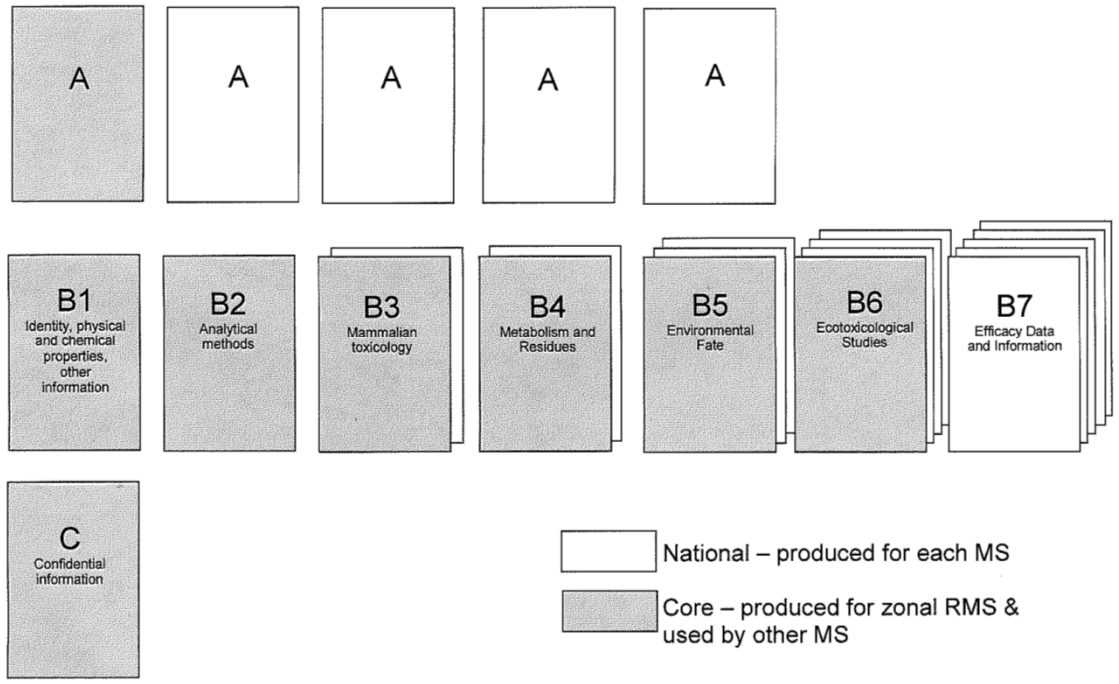
Zones for authorisation of PPP



Structure of a zonal dossier

SANCO/6895/2009



Zonal authorisation process

- Identify Zonal Rapporteur Member State (zRMS):
  - Submit request through notification form least 6 months before;
  - Request a pre-submission meeting to ensure completeness of dossier
- Preparation of a zonal registration dossier
  - Core dossier using «worst cases» risk envelope approach
  - With a « zonal » BAD (considering EPPO zones)
  - With national addenda meeting the specific national requirements
- Submission of the dossier:
  - To the zRMS and other MS in the zone **where a registration is requested or renewed**;
  - Core dossier and national addenda may be different to cover specific requirements
- Evaluation and authorization in the zRMS 1 year from submission
- Authorization in the other MS within 120 days
  - Any mutual recognitions also follow this timing

Raising issues

- Capacity at MS level is limited:
  - Rejection of MS to act as zRMS
  - Queue for submission is around 1 to 2 years (depending on the MS)
  - Progress on national submission may be very slow
    - ✓ 5 years expected in Germany;
    - ✓ Unclear for most countries.
- No fit between the different defined zones :
  - PPP authorisation zones
  - EPPO zones
  - Residue zones

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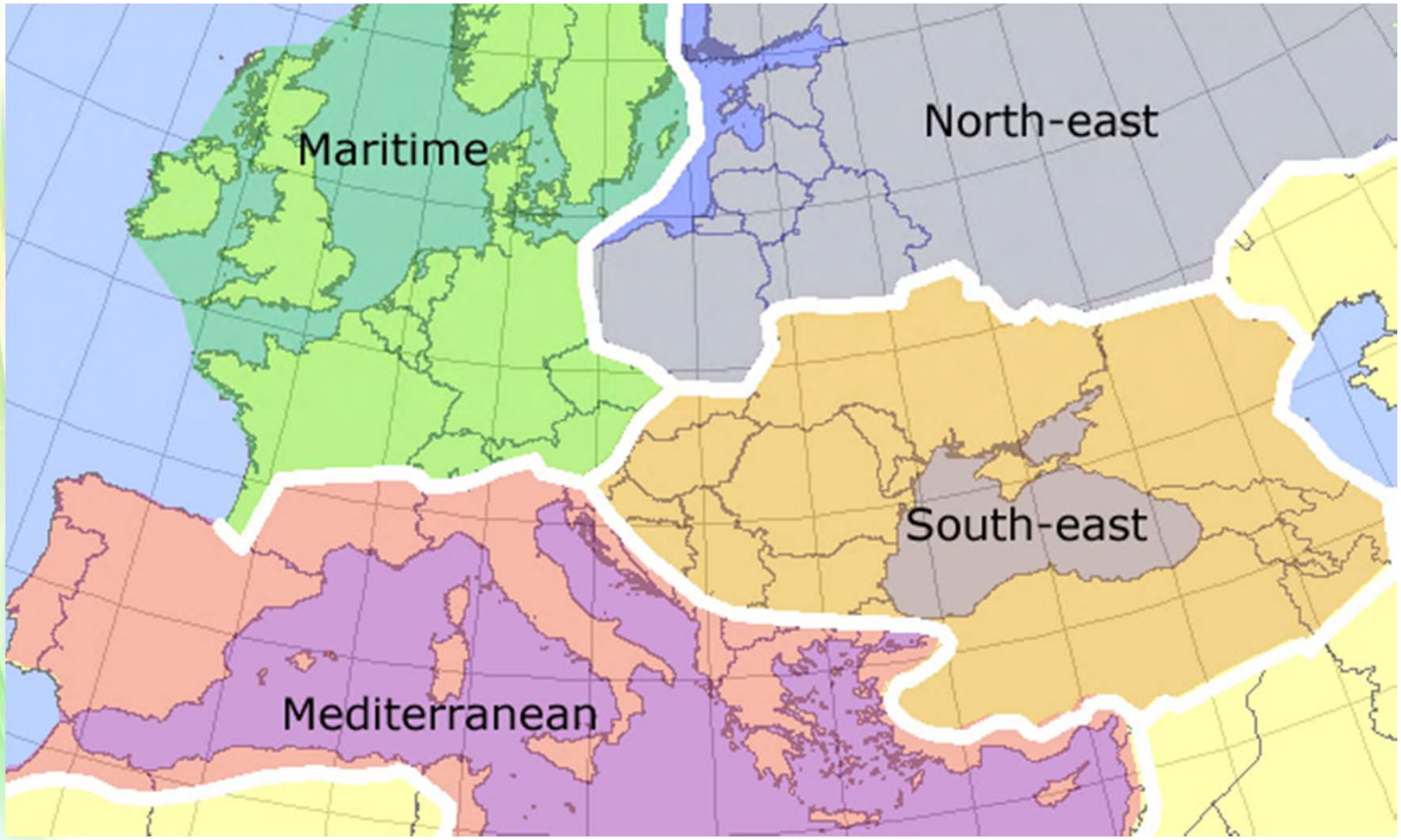
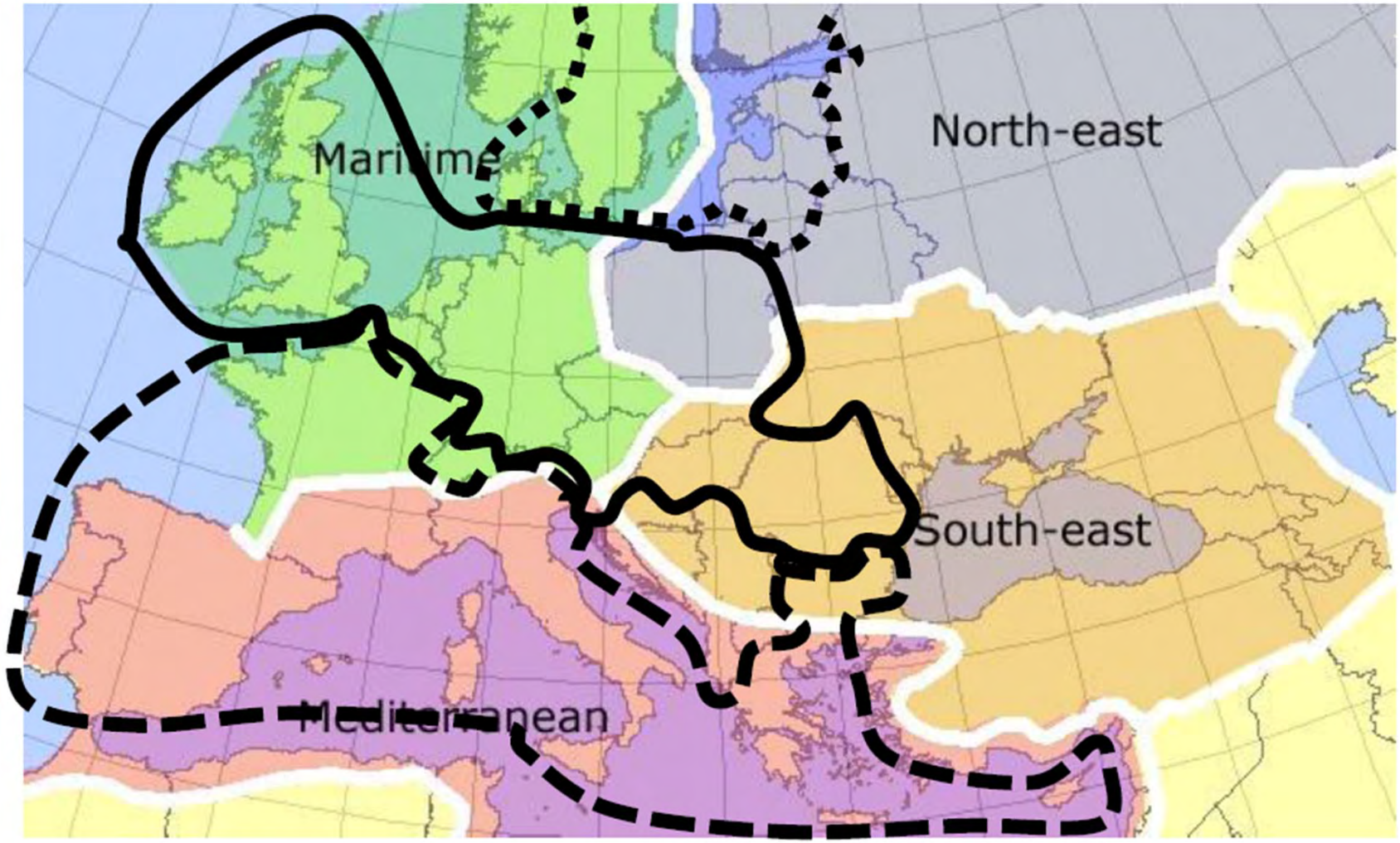
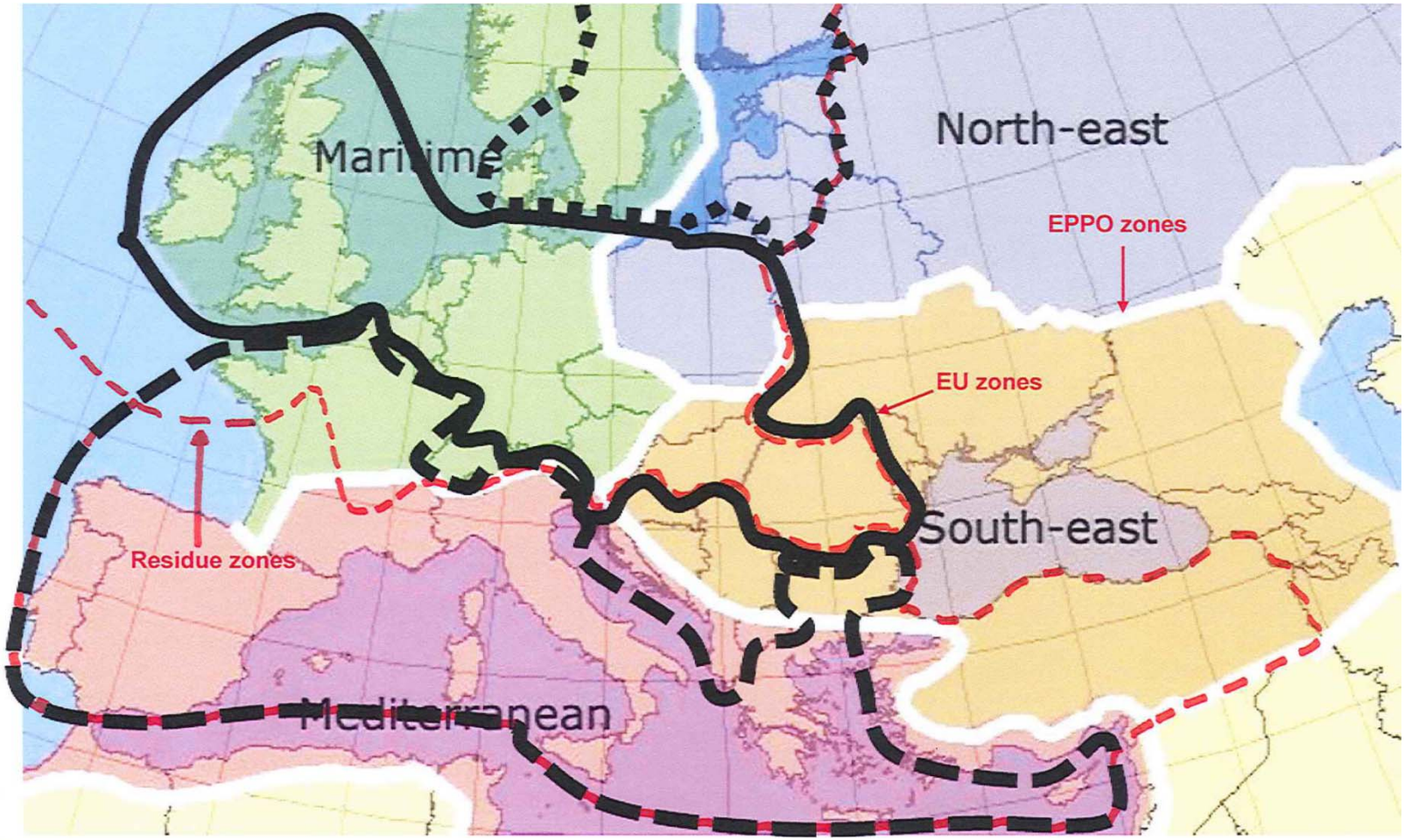
EPPO Zones



EPPO + Defined PPP zones



EPPO zones + Defined PPP zones + Residue zones



Further issues

- Dossier has to be complete:
  - Submission delay if a study triggered by the risk envelope approach;
  - Need to support all crops relevant in the zone (BAD not always complete for all crops);
  - Need to submit at the same time your core dossier and national addenda in the countries;
  - No flexibility to add further information during the evaluation.
- Once a zonal submission is made, only Mutual Recognitions (MR) can be granted in the zone.
  - In case a MS dossier is late waiting for efficacy data; only a MR can be granted;
- In case a label extension is require a further zonal dossier must be submitted.

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Consequences for Industry

- Plan in advance which MS registrations are required:
  - National addenda need to take into consideration requirement for the country e.g. risk assessment
  - Zonal system is more appropriate for integrated multinational industry than SME
    - ✓ Dossier is for a single applicant
    - ✓ Cost reformatting the dossier
    - ✓ Core dossier and national addenda to be submitted simultaneously
    - ✓ Dossier needs to integrated with national knowledge
- Need to plan the submissions at least 3 years in advance:
  - 2 years efficacy & residue trials (where required)
  - 1 year reporting and dossier preparation

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Thank you!

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