# Epidemiological outcome: some key questions of regulatory managers

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Stakeholder workshop on Pesticide epidemiology,
Paris, 18 Feb 2015

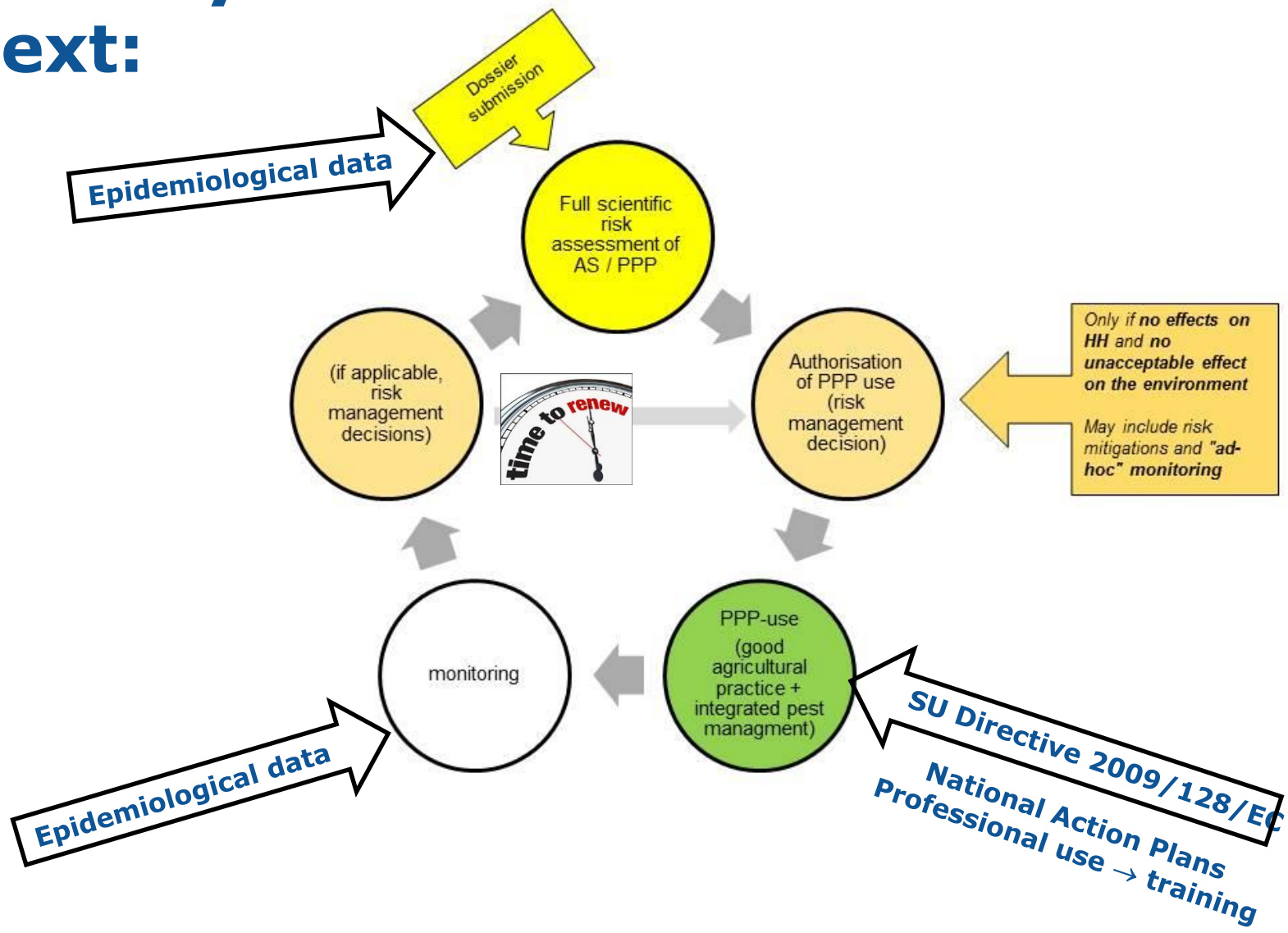
# Who are the "risk managers" (EU)?

**Active substances approval**

**PPP-use authorisation**

**Regulation (EC) No 1007/2009**

# Regulatory context:



# COMMISSION REGULATION (EU) No 283/2013 (data reqs. AS)

- **5.9.4. Epidemiological studies,** Relevant epidemiological studies shall be submitted, where available.

- **5.9. Medical data**

… Data …relevant to the effects of human exposure, where available, shall be used to confirm the validity … with respect to target organs, dose-response relationships, and the reversibility of adverse effects. Such data may be generated following accidental, occupational exposure or incidents of intentional self-poisoning…

# Regulation (EC) No 1007/2009

- *Recital 13:*

For ethical reasons, the assessment of an AS or a PPP ***should not be based*** on tests or studies involving the ***deliberate administration*** of the AS or PPPs to humans … Similarly, toxicological studies carried out on humans should not be used to lower the safety margins for AS or PPPs.


# RM questions

- *when designing epidemiological studies*
- *when analysing results of epidemiological studies*


# generalities…

***basics***

→ *representativity (no of samples ?)*

→ *plausibility (correlations?)*

***to keep in mind*** → *RM decisions based on:*

- *single AS or PPP use*
- *under specific conditions of use (e.g. restrictions, maximum levels, protective equipments)*


# When designing epidemiological studies…

- *the link observed effect – exposure is crucial*
- *prioritisation vs. Broad scope?*
- *if prioritisation:*
  - **Which AS? (e.g. candidates for substitution? AS prioritised via National Action Plans (SUD)?…)**
  - **To focus on which population groups? (e.g. kind of exposure, age, ….?)**


# When analysing results…

*- link to particular (group of) active substances*

- **Approved/non approved AS?**

*- exposure*

- **Over time: single exposure, repeated exposure, levels of exposure, how did exposure change over time?** (AS taken off the EU market in last 20 years)
- **Which kind of PPP-use? Authorised? Accidental?**
- **Key exposure route via PPP use?** (some AS may have also other uses, adding further exposure routes)

European Commission