



SEA & its Role in Decision-Making

Workshop on Socio-economic analysis in applications for authorisation and restrictions under REACH

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Socio-economic Analysis (SEA)

- **WHAT?**

- Methodological approach to identify & analyse relevant impacts
 - Who is affected and in what way – both on risk and cost side
 - Overall costs and benefits of a measure
 - Trade-offs, distributional effects, SMEs, employment, affordability
- Outlined in Annex XVI of REACH
 - Economic, social, health and environmental impacts

- **WHY?**

- Prescribed by REACH
- Replaces the need for an Impact Assessment
- Informs the decision-making

SEA in Restrictions – WHY? (1)

- **REACH Article 68(1)**
 - *'...Any such decision shall take into account the socio-economic impact of the restriction, including the availability of alternatives'*
- REACH Article 69 - *Preparation of a proposal / Annex XV*
- REACH Article 71 (1)
 - *'...the Committee for Socio-economic Analysis shall formulate an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact...'*
- REACH Annex XV
 - *'... (i) effectiveness: the restriction must be targeted to the effects or exposures that cause the risks identified, capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk;'*

SEA in Restrictions – WHY? (2)

- **Better Regulation/ COM Impact Assessment**

- 'Better Regulation' – designing EU laws so that they achieve their objectives at minimum cost
- An IA is required for COM initiatives that are likely to have significant economic, environment or social impacts

- **Replaces the need for an Impact Assessment**

- Pre REACH Restrictions: (Risk Assessment (RA) and Risk Management Measures (RMM) by Member States (MS) >> Commission (COM) Proposal + COM Impact Assessment (IA)
- REACH restrictions: (Annex XV by MS/ECHA(COM) >> RAC/SEAC Opinion/BD >> COM Proposal // Annex XV + RAC/SEAC opinion + BD – sufficient basis for COM decision

SEA in Authorisation – WHY?

- REACH Article 60(4)

- *'...an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance...This decision shall be taken after consideration of... the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties.'*

- REACH Article 60(8)

- *'...the duration of the time-limited review...taking into account all relevant information including the elements listed in paragraph 4(a) to (d)...'*

- REACH Article 62(5)

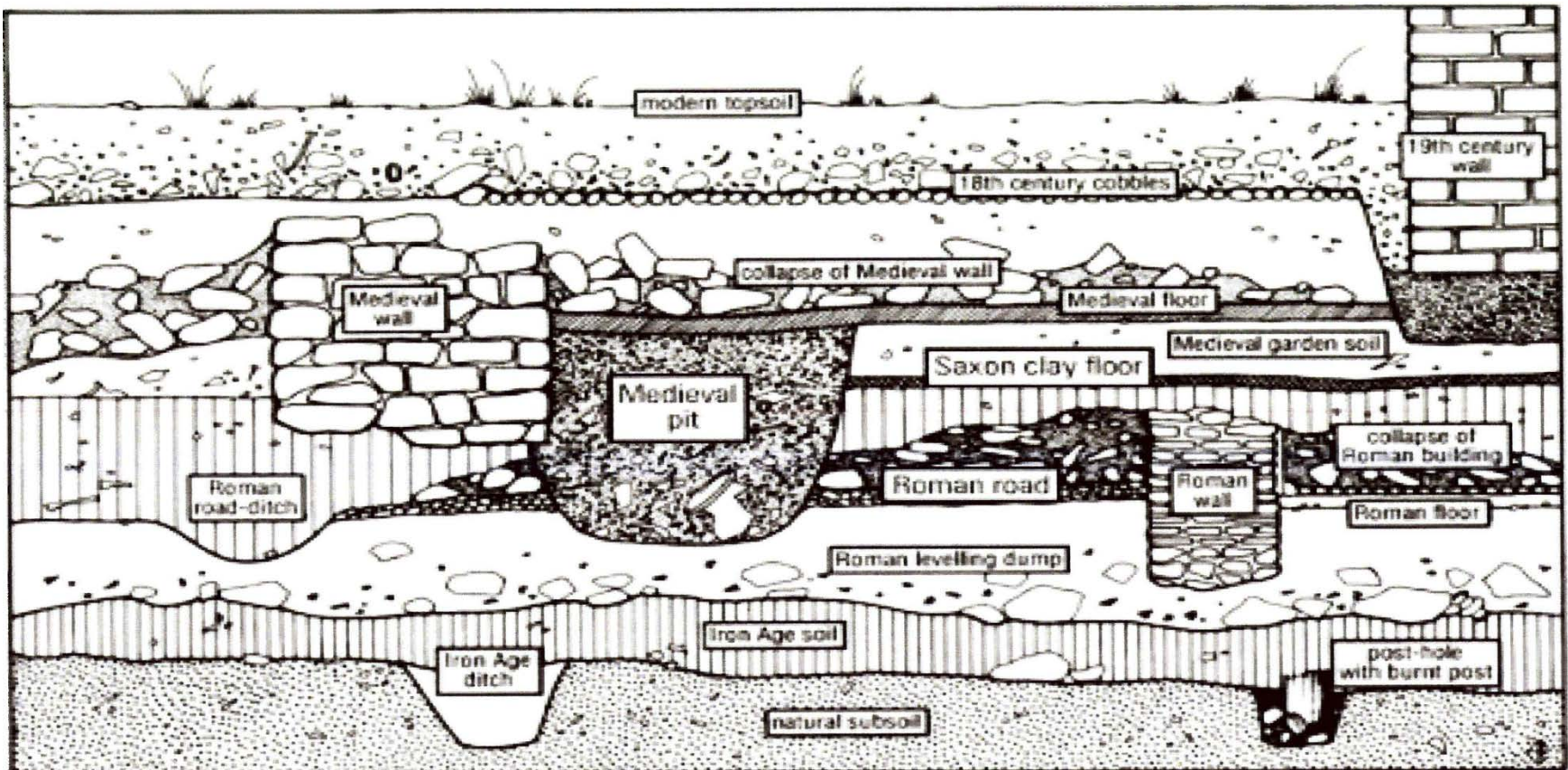
- *'The application may include: (a) a socio-economic analysis conducted in accordance with Annex XVI'*

- REACH Article 64(4)(b)

- *'... and assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives...'*

WHAT DOES SOCIO-ECONOMIC ANALYSIS TRY TO ACHIEVE?

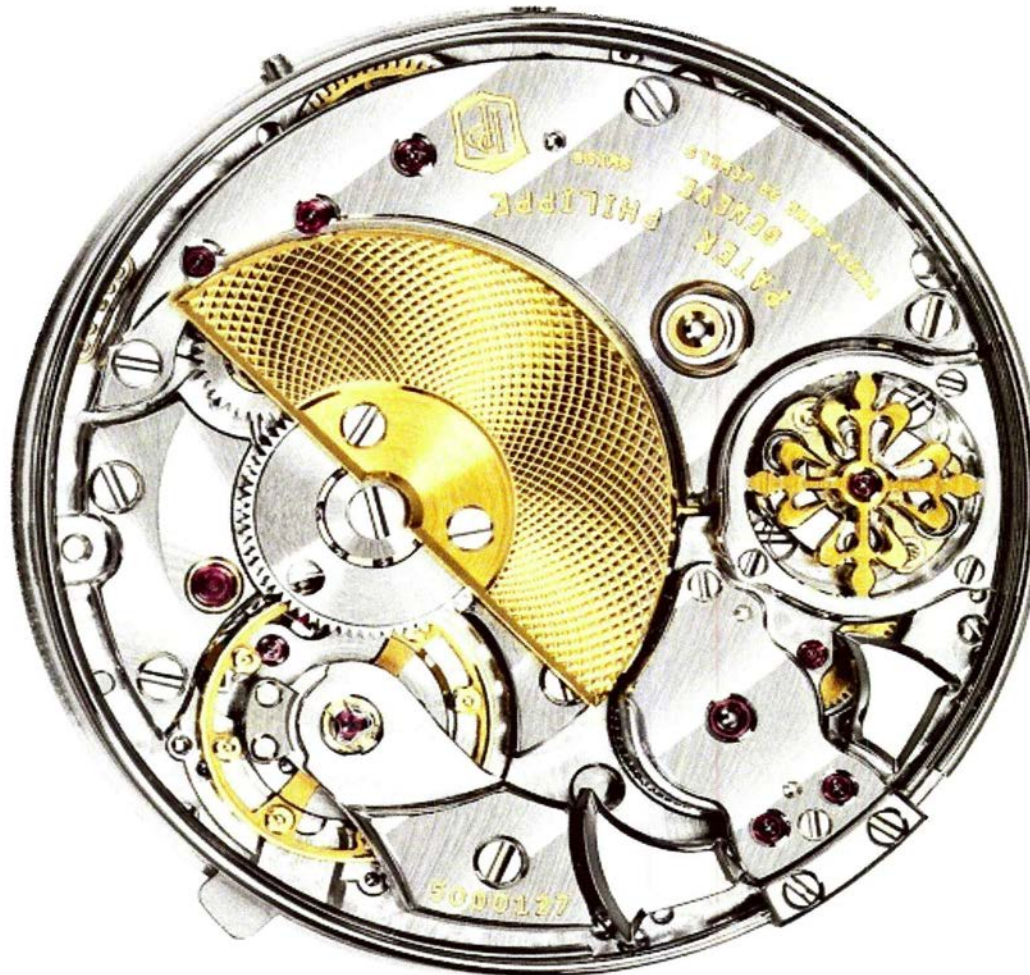
... to add another layer to an already complex decision-making?



.... fulfil the rules set by the legislators?



....help in developing an effective, efficient
and coherent EU regulatory measure?



Conclusion/Discussion

- **SEA IS & ISN'T**
 - A tool - not a solution
 - Informs - does not decide
 - Sets an evidence framework - but is not a substitute for political judgement
 - Reduces uncertainties
- **Challenges**
 - Conceptual?
 - Methodological? Operational?
 - Communicational?



Thank you for your attention!

