

What happens if regulation is not adaptive?

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The European perspective

- **Regulation** is made by the Executive of Government and is administrative in nature
- **Policy** is made by individuals, organisations or Governments and is general in nature
- **Legislation** is a legal directive usually imposed by Government – regulation is a specific requirement within legislation

As we all know there is hardly anything
(bad) the EU is not responsible for....

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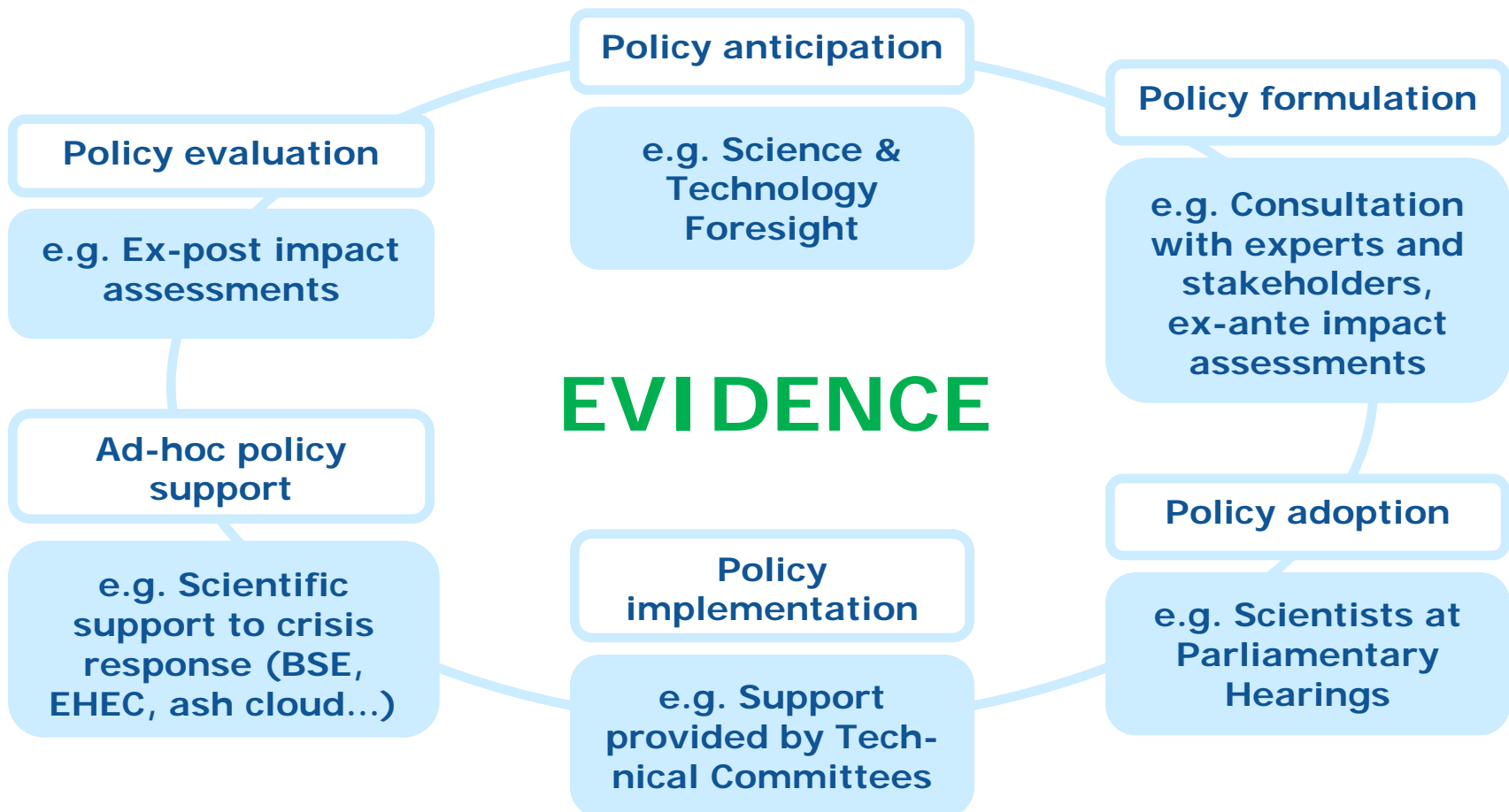
Flooding: Somerset Levels disaster is being driven by EU policy

EU directives actually require certain plains to become flooded



How is regulation developed?

Science in the EU policy cycle



SCIENTIFIC EVIDENCE

Academies and
Learned Societies

Chief Scientific
Adviser/Science
Advice
Mechanism

Joint Research
Centre (JRC)

Scientific
Committees and
Expert Groups
PSTAC

European science
associations (e.g.
EASAC, Euro-CASE,
ALLEA)

National
research-performing
organisations and
universities

European research
organisations
(e.g. ESA, EMBL...)

Industrial R&D

EU Agencies (e.g.
EFSA, EMA, ECDC)

Citizen science

What next?

- Evidence is gathered and synthesised
- Impact assessments are carried out
- Policy is proposed
- The Commission delivers its proposals to Parliament
- Parliament debates and amends
- Iteration
- Council decides

Many political decisions in the EU depend on science and engineering



A Single Sky in Europe

Developing common rules for European aviation

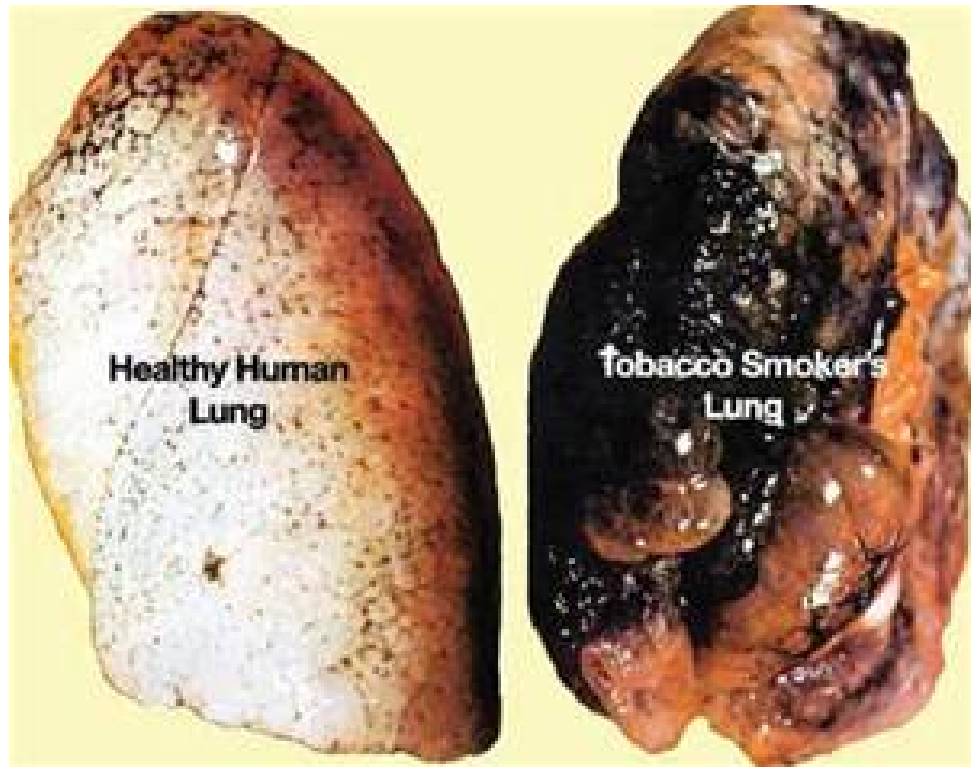


He's one of the busiest men in town. While his door may say *Office Hours 2 to 4*, he's actually on call 24 hours a day.

The doctor is a scientist, a diplomat, and a friendly sympathetic human being all in one, no matter how long and hard his schedule.

According to a recent Nationwide survey:

MORE DOCTORS SMOKE CAMELS
THAN ANY OTHER CIGARETTE



Healthy Human Lung

Tobacco Smoker's Lung

There is often uncertainty

"I am taking a shot in the dark here"

"I am almost certain, but there are still a few remaining doubts to clear up"



Communicating risk

- High risk – low impact
- Low risk – high impact
- Role of media attention
- Tweetification of risk

Biofuel regulation

- Environmental regulation
- 1st generation biofuels – bioethanol/biodiesel
- Regulation introduced
- Regulation encourages business to invest
- Unintended land use change becomes apparent
- Food security issues
- Challenge to adapt regulation (2012)

Adapted regulation

- Contribution of 1st gen biofuels to 10% renewables target for transport – capped at 7%
 - **Remaining 3% to come from used cooking oils**
 - **Renewable electricity for cars/vans/rail**
 - **2nd and 3rd gen biofuels**
- Approved by EP April 2015

What happens when regulation not adaptive?

- Meaningful investment in biofuels in EU stopped by 2012
- The EU regulatory environment is not attracting longterm investment
- Environmental objectives are not being met
- Internal conflict
 - **Climate**
 - **Energy**
 - **Environment**
 - **Transport**
 - **Industry/Trade**

A successful example?

- **Adaptive pathways** approach at EMA
- Doesn't change **standards for evaluation of benefits and risks** of medicine
- Approval in stages (restricted patient population then expanding)
- Gathering evidence through real-life use to supplement clinical trial data
- Early involvement of patients and health/technology assessment bodies in discussions on a medicine's development

Thank you for your attention!

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