European Crop Protection

Public availability and financing of studies

An industry perspective

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Background?

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European Parliament Resolution; 24th October 2017:

- **the transparency and public availability of scientific studies** *[among the evidence used by EFSA and ECHA for their evaluation]*, as well as of the raw data on which these studies are based, are of the utmost importance**;**
- Commission and the Member States to ensure that the scientific **evaluation** of pesticides for EU regulatory approval is **based only on published peer-reviewed and independent studies commissioned by competent public authorities**
- EFSA and ECHA should be granted sufficient resources in order increase their capacity, to **enable the commissioning of independent scientific studies and to further ensure that the highest scientific standards are upheld**

Public availability of studies

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- **As a principle the crop protection industry understand the need for public access**

- **Need to consider**
  - What is being requested by the public?
  - What needs to be protected?
  - What is available / possible for the future?

What data is currently available?

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	Pages	Public
Company dossier:		
– **Detailed summary dossier**	**3000**	**Yes**
– Detailed regulatory dossier	50000	No
– Post-registration monitoring (resistance…)	500	No
Authority evaluation:		
– Draft Assessment Report (volume 1-3)	1500	Yes
– Draft Assessment Report volume 4	60	No
– **Peer review report**	**700**	**Yes**
– **EFSA conclusions and endpoints**	**100**	**Yes**
– Commission review report	10	Yes
– EFSA reasoned opinions on MRLs	100	Yes
– ECHA CLH evaluation	100	Yes
Total pages EU	**56000**	**~6000**

More data available on PPP evaluations than all other regulated sector

Public availability of studies

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- **What is being requested by the public?**
  - All studies?
  - Summaries?
  - Detailed data tables (for verification)?
- **Does the public know what is now available?**
  - How can me make that visible?

Public availability of studies

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- **What needs to be protected?**
  - Some data still needs to be kept confidential
    - Personal data
    - Business confidential
- **What is available / possible for the future?**
  - Pharma industry – what is relevant here?
  - Reading room – allows verification
  - Data tables – EFSA initiative

Industry is looking at options that can provide real benefits in ensuring greater trust in the process!

‘Independent’ studies

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- **If studies have to be ‘independent from industry’, what are the options?**
  - Industry require prior agreement of a designated authority for each study
  - Industry pay authority who choose the research facility
  - Industry pays authority to carry out the study ‘in-house’
  - Authority carries out studies from own budget (paid by industry tax/fee?)

‘Independent’ studies

What are the main challenges?

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- **If done for pesticides, what about other sectors** (pharma, chemicals, cosmetics, etc…)?
- **Would this fit with third countries?**
- **Impact on animal testing** (repeat testing)**?**
- **How would government funding be managed** (and protected!)**?**
- **Do governments have resources to manage?**
- **Would NGOs stop challenging independence?**
- **How would “independence” be established?**
- **What impact would this have on innovation?**

‘Independent’ studies

Industry view

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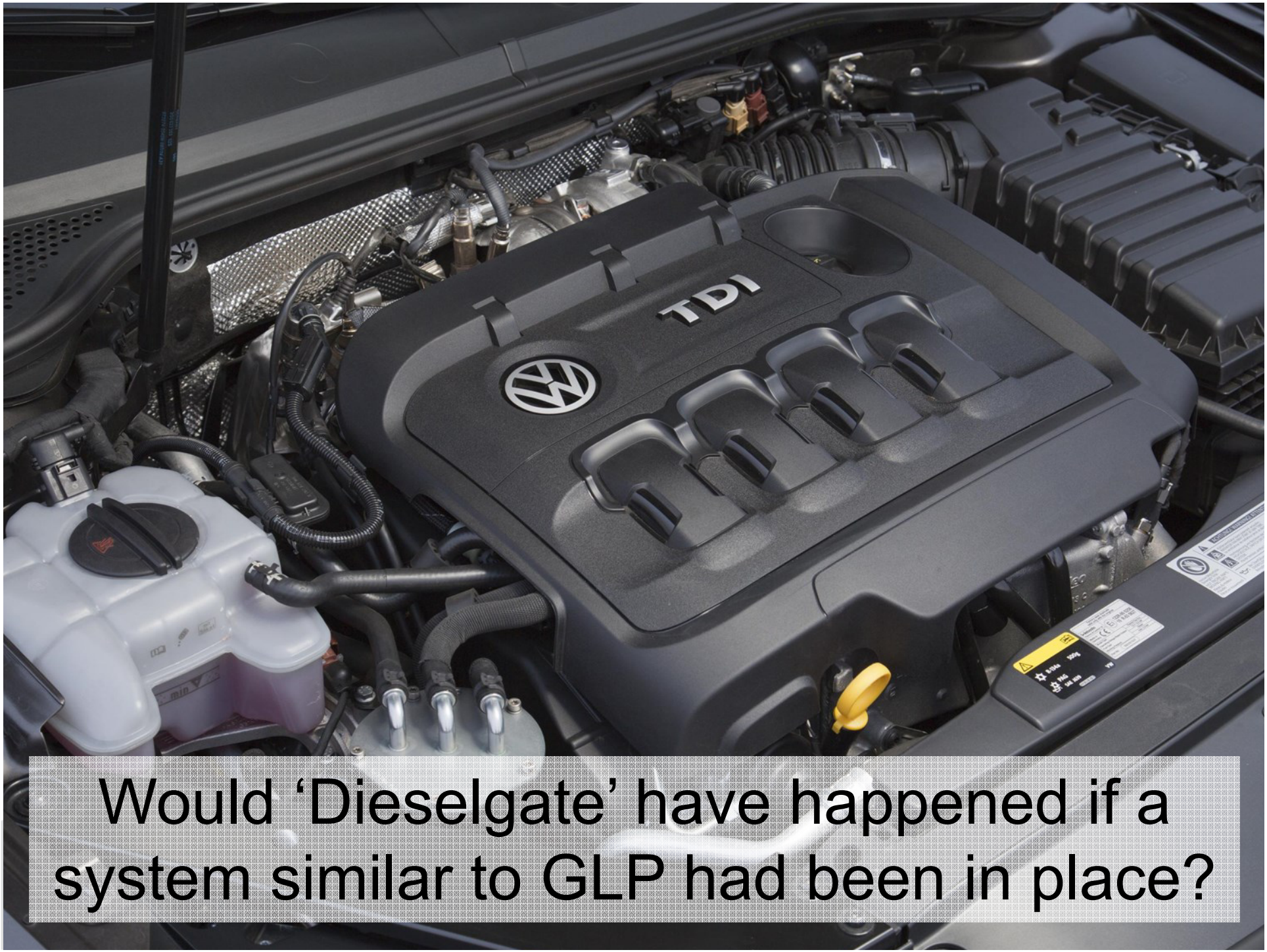
- GLP and testing guidelines provide high level independent check that is accepted, understood and trusted by science
- Fully support a system where studies need to be independently verified ***- as is currently the case***
- Creating authorities to carry out all studies is unrealistic and would take many years
- Need a system that is consistent between sectors and with third countries
- Would create the need for repeat testing – ***increase in animal testing would be completely unacceptable!***

Focus should be on independent verification – not independent study ownership!



Would ‘Dieselgate’ have happened if a system similar to GLP had been in place?

Relevance and reliability of data

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- All available studies should be taken into account in regulatory decisions
- Greater weight should be given for quality, relevance and reliability
- GLP studies based on OECD test guideline are important to ensure quality and consistency
- GLP and OECD TGs are not a guarantee of relevance but allow regulators (and others) to understand and replicate if required

Conclusion

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- **Public availability of studies**
  - Support data transparency
  - Need to highlight data already available
  - Industry is looking at further options
  - Need benefits to ensure trust in regulatory process!

- **Public financing of 'independent' studies**
  - Quality of science is key
  - Support innovation and minimise animal use
  - Public system in EU would be complex & out of step
  - Focus should be on independent verification

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THANK YOU