



Public availability and financing of studies

An industry perspective

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Background?

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**

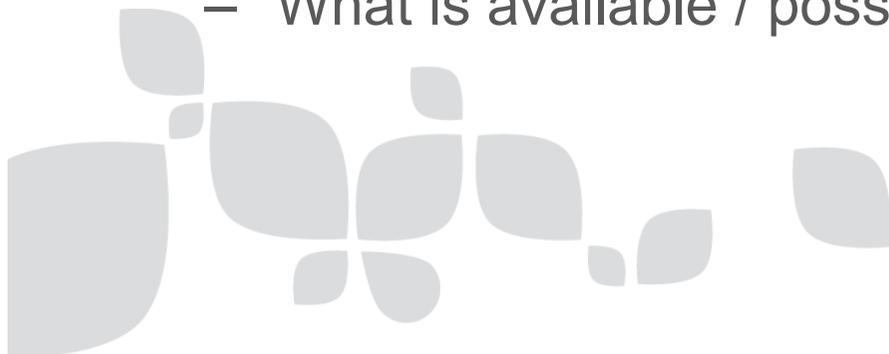
Public availability of studies



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?



	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

What is being requested by the public?

- All studies?
- Summaries?
- Detailed data tables (for verification)?

“All information should be published”

Does the public know what is now available?

- How can we make that visible?

“Stop blinding us with science, too much information”

Public availability of studies



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

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?

- **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?**

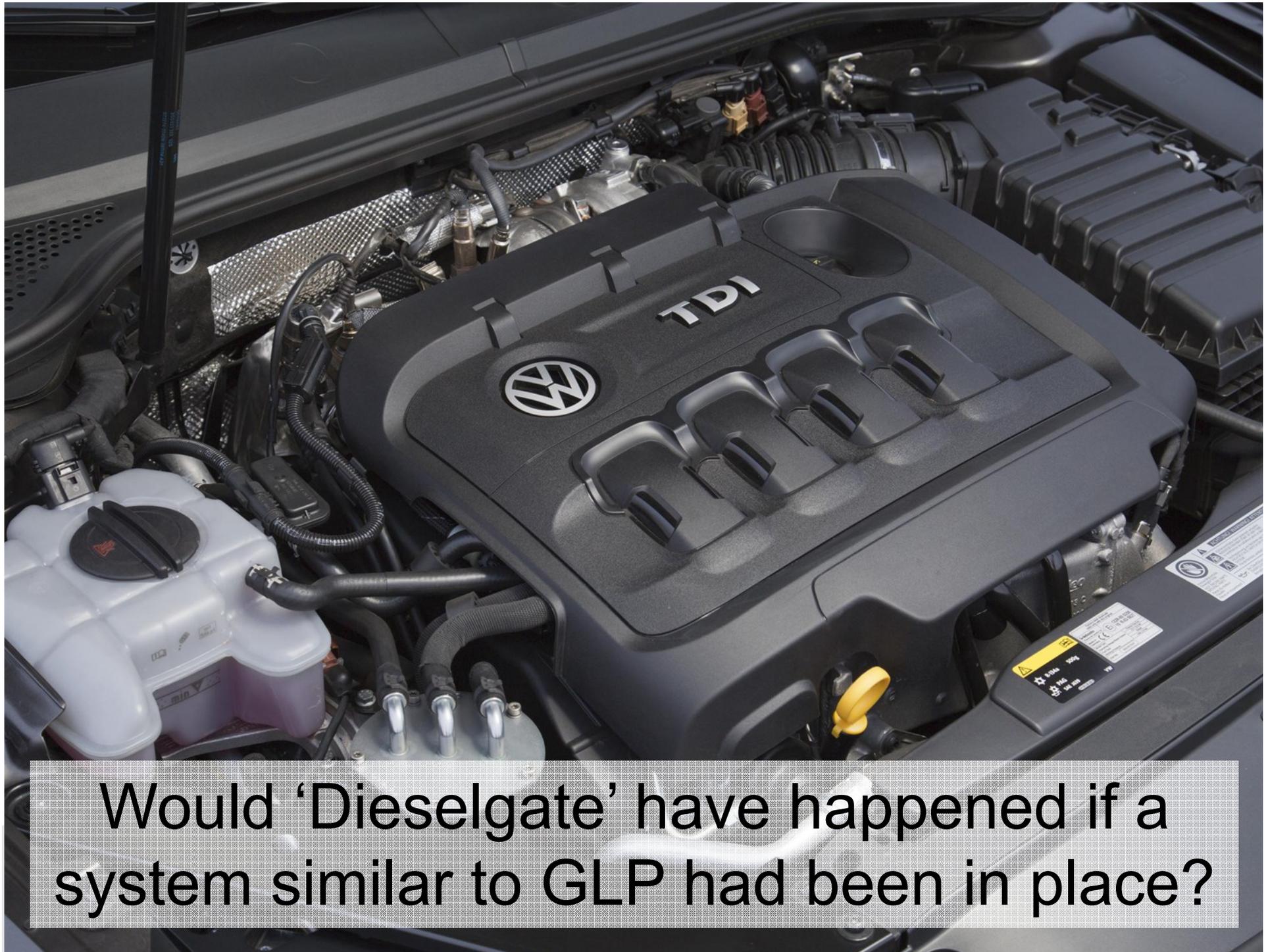
'Independent' studies

Industry view



- ▶ 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



- 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

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



THANK YOU