

Overlapping GMO requirements for medicines in the EU

INNO4VAC Stakeholders meeting

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Dr. Joris Vandeputte



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Overlapping principles

- *Legislation on human (Directive 2001/83/EC and animal medicines (Reg 2019/06) clearly determine requirements for environmental release*
- *These requirements date from before GMO legislation Dir. 2001/18*
- *Directive 2001/18 was initiated to regulate environmental release of GMO produced plants*
- *However, the directive 2001/18 does not mention plants*
- *Release requirements of directive 2001/18 overlap pre-existing requirements by medicines legislations*

Overlapping Environment Risk Assessment (ERA)

	Dir. 2001/18	Reg. 2019/006	Dir. 2001/83 as amended
General principles	Annex II	Annex I	Annex I Part I
Methodology Characteristics GMO	Annex II C1	Annex I Annex II Title 1, Part 2,3 Annex II Title 2, Part 2,3	Annex I Part I
Steps in ERA	Annex II C.2	Annex II, Title 1, Part 3.6 Annex II, Title 2, Part 3D	Annex I Part I
Conclusions	Annex II D.1	Annex II, Title 1, Part 1 Annex II, Title 2, Part 1	Annex I Part I

Overlapping information requests

	Dir. 2001/18	Reg. 2019/006	Dir. 2001/83 as amended
General information on release	Annex III. I	Art 10	Art 11
Donor	Annex III. II. A	Annex II, Title 1, Part 2,3 Annex II, Title 2, Part 2	Module 1,2,3
Vector	Annex III. II. B	Annex II, Title 1, Part 2,3 Annex II, Title 2, Part 2	Module 1,2,3
Modified organism	Annex III. II. C	Annex II, Title 1, Part 2,3 Annex II, Title 2, Part 2	Module 1,2,3

Overlapping Release

	Dir. 2001/18	Reg. 2019/006	Dir. 2001/83 as amended
Release	Annex III. III A	Annex II, Title 1, Part 4 Annex II, Title 2, Part 3	Module 5
Environment	Annex III. III B	Annex II, Title 1, Part 3 Annex II, Title 2, Part 3	Annex I, Module 3 Attachment
Interaction GMO- Environment	Annex III. IV		
Survival, dissimination, multiplication	Annex III. IV A		
Environment	Annex III IV B		

Overlapping monitoring, labelling

	Dir. 2001/18	Reg. 2019/006	Dir. 2001/83 as amended
Monitoring techniques	Annex III. V A	Art. 8	Art 8
Release control	Annex III. V B	Art 73, 123	Artt 21a, 101
Waste treatment	Annex III. V C	Art 35, 117	Artt 8, 54, 54a
Emergency	Annex III. V D	Artt 129, 134	Artt 106, 107i
Placing on market and labelling	Annex IV	Art 35	Artt 22a,b, 54, 59

Competent authorities and Procedures

Legal Provision	Competent Authorities	Procedures
Dir. 2009/41	Big variety in all EU-Member States Regional /local competent authorities + ministries	National authority shares national notification with other MS and EU-COM
Dir. 2001/18	One competent Ministry per Member State	National authorities share assessment with other MS and EU-COM
Dir.2001/83	One competent Agency per Member State	Centralised procedure at EMA, authorities, competent for GMO are involved
Reg.2009/06	One competent Agency per Member State	Centralised procedure at EMA, authorities, competent for GMO are involved

Conclusion and suggestions

- Highest possible degree of safety of medicines, including those issued from GMO technology has to be required without discussion
- Three legal frameworks ask for the same
- Possibility to exempt from directives 2001/18 and 2009/41 for medicines complying within their respective legislations?

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