



Synthetic biology and GMOs

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Workshop on Synthetic Biology
From Science to policy and societal challenges
Esch-Sur-Alzette, Luxembourg
10 December 2015

Scientific Committees: a science-based operational definition of SynBio

SynBio is the application of science, technology and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organisms.

Scientific Committees: a science-based operational definition of SynBio

However the Scientific Committees recognised that:

It is difficult to accurately define the relationship between genetic modification and SynBio on the basis of quantifiable and currently measurable inclusion and exclusion criteria.

After extensive debate, the conclusion was that attempting to identify a clear separation between GM and SynBio is currently not practical.

The relationship between SynBio and GM

Developments in GM Area

Projected short- to medium term developments of GM/SynBio

New GM technologies since around 2000 = emergence of the SynBio metaphor

Establishing the core toolbox of Genetic Modification (until around 2000)

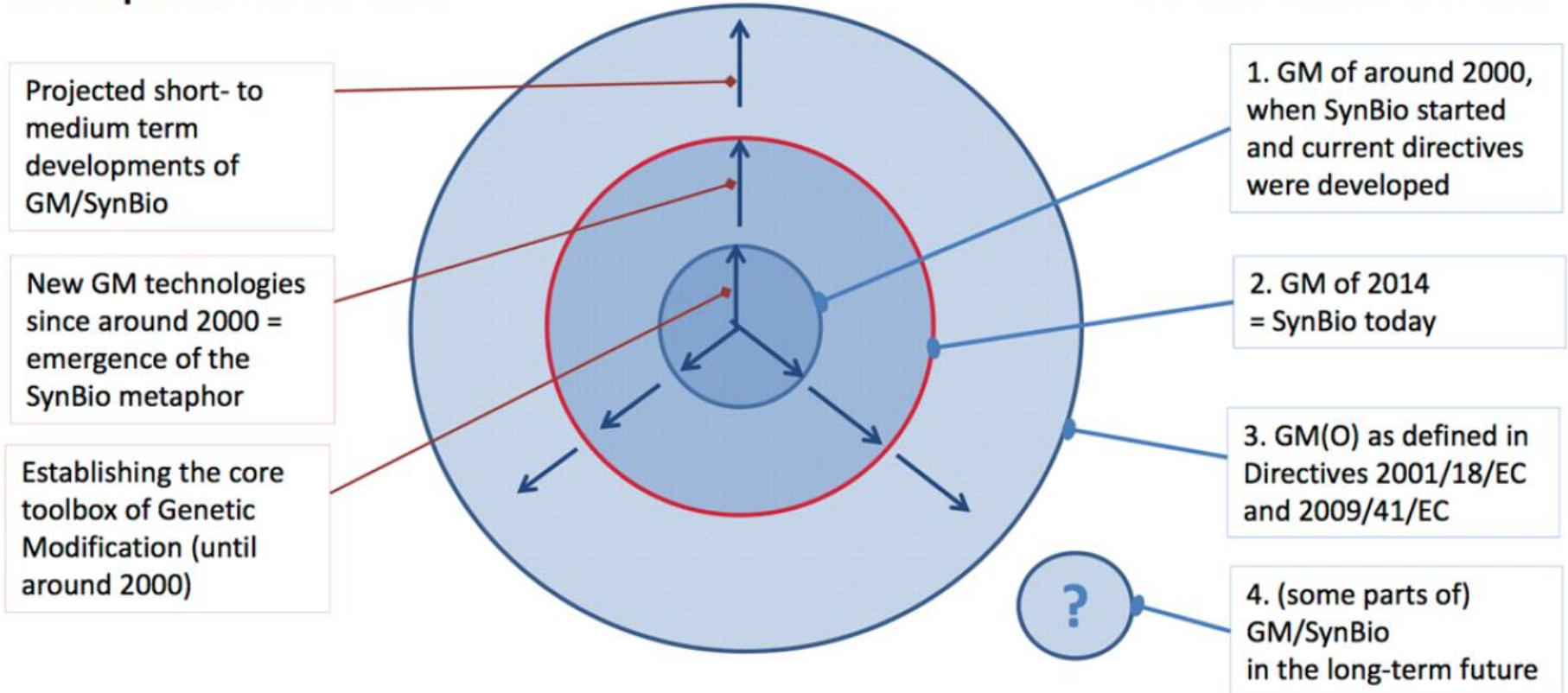
Relevant Reference Points

1. GM of around 2000, when SynBio started and current directives were developed

2. GM of 2014 = SynBio today

3. GM(O) as defined in Directives 2001/18/EC and 2009/41/EC

4. (some parts of) GM/SynBio in the long-term future



The relationship between SynBio and GM

The fourth reference point will be our challenge:

- We will have to assess whether SynBio applications in the long-term future will be falling under the scope of the existing GMO legislation.
- In case they won't be, we will have to assess whether there is a need for amended/new legislation or not.

Assessing whether SynBio applications in the long-term future will fall under the existing GMO legislation

This may require a legal interpretation, which will have to consider that:

- The legislation has been drafted when SynBio was starting to be developed.
- SynBio is a concept which is not referring to specific techniques.

"New breeding techniques" (NBTs)

A similar process is being currently undertaken by the European Commission to assess whether organisms produced by a number of "new breeding techniques" fall under the scope of the EU GMO legislation.

The Commission legal analysis on NBTs

Elements for consideration:

- Definition of GMO: it is common to Directive 2001/18/EC and Regulation (EC) No 1829/2003. In Directive 2009/41/EC on the contained use of GMM, the notion of GMM is largely inspired by this definition.
- Eligibility for exemption of GMOs and GMMs obtained through certain techniques under certain conditions.

The Commission legal analysis on NBTs

- It will be a Commission's legal interpretation.
- It will address specific techniques, but it will also provide some general lines of interpretation which can be applied horizontally to different techniques and to potential future developments.
- It will provide interpretative principles which could be applied to synthetic biology applications.

The Commission legal analysis on NBTs

- It is planned to be adopted in the first quarter of 2016.
- Before adoption, it will be presented to Member States and stakeholders.



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THANK YOU