



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

New Developments in Biotechnology

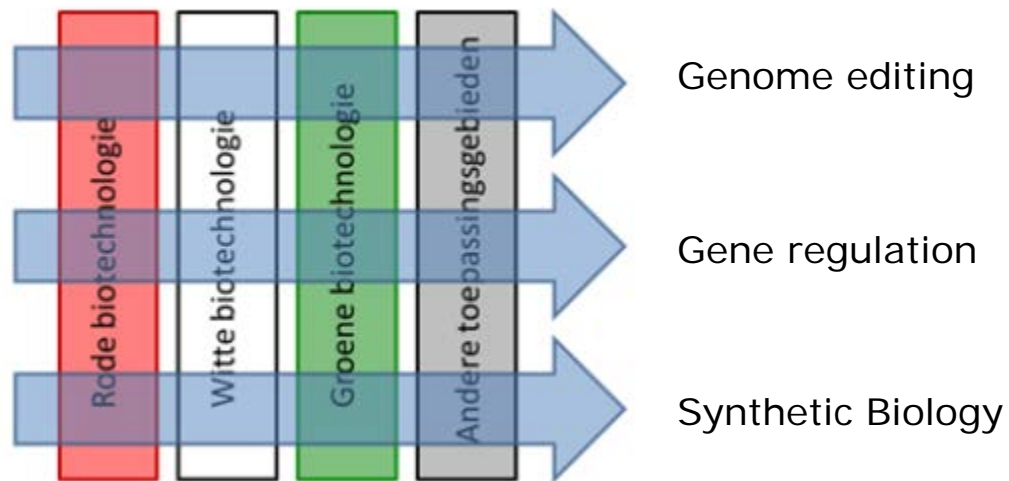
Consequences for Risk
Assessment

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New Developments in Biotechnology | November 23th
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Inventarisation of new developments



RIVM reports:

Emerging Gene Expression and Gene Expression Regulation Technologies in Medical Biotechnology

Analysis of new developments in white (industrial) biotechnology

New developments in green biotechnology

<https://biotechnologie.rivm.nl/>



Consequences for Risk Assessment

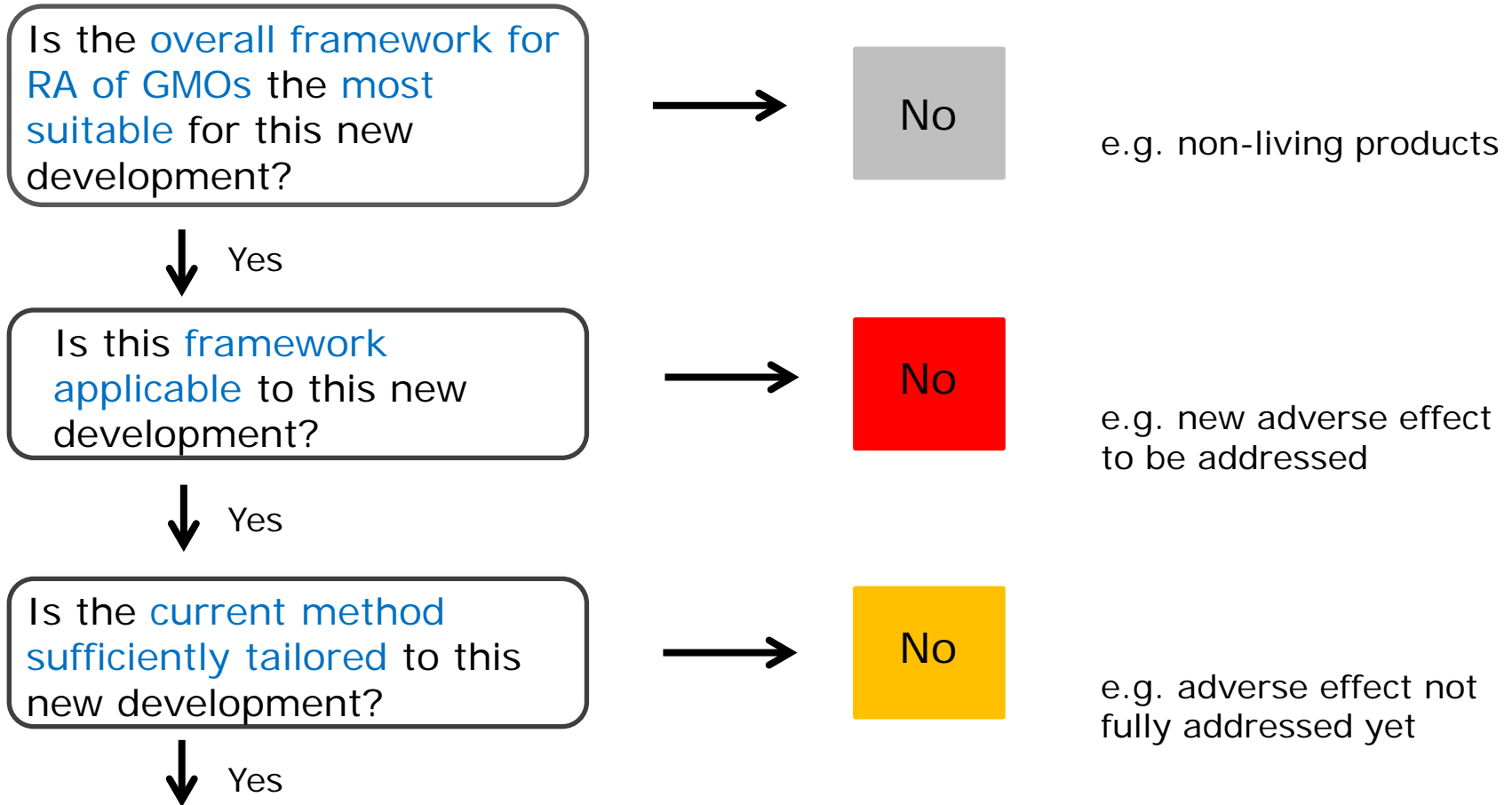
Are current risk assessment (RA) methods still applicable to assess the safety for human health and the environment of the new developments?

RA **methods** according to **frameworks** of 2009/41/EC (Contained Use) and 2001/18/EC (Deliberate Release)

 Decision Tree

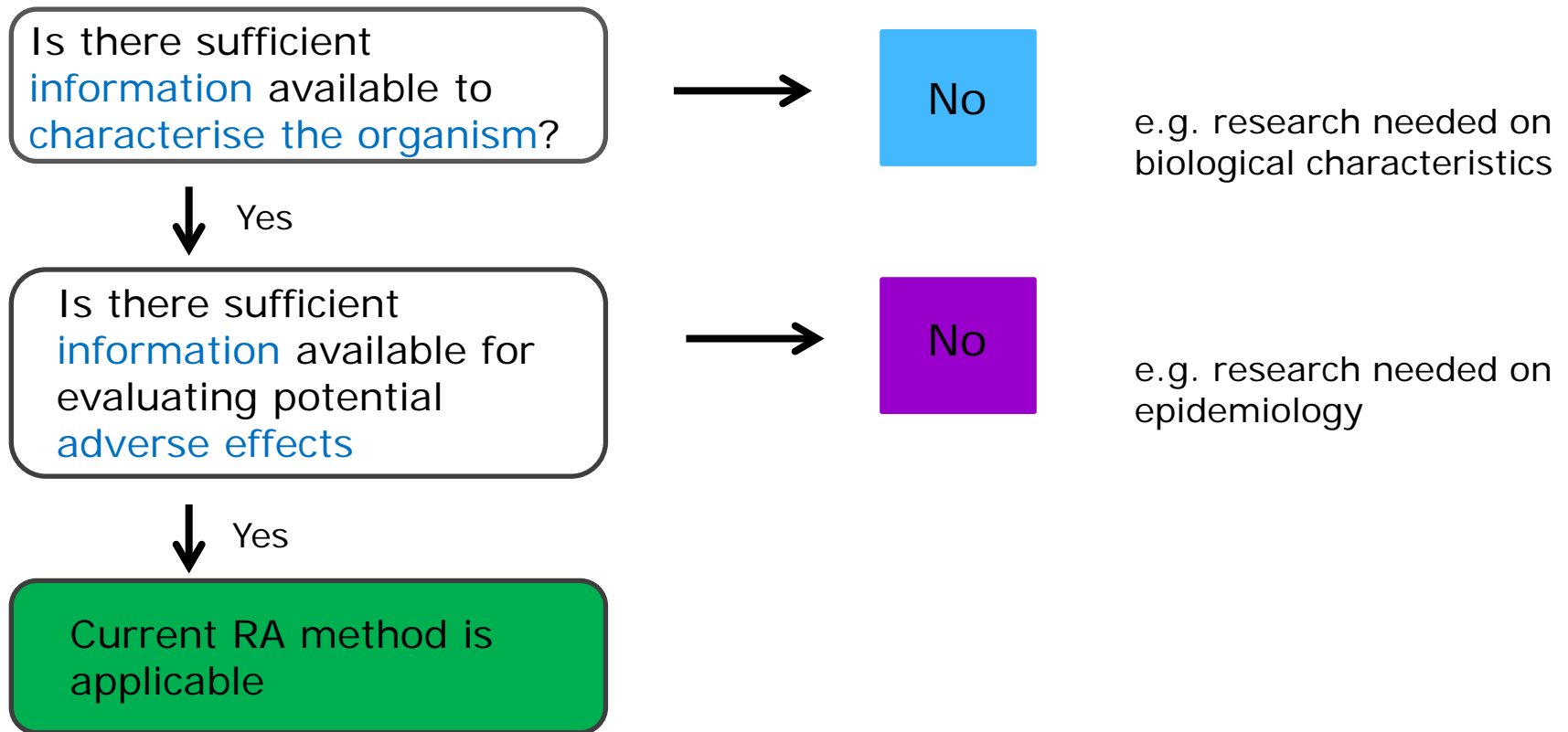


Risk Assessment (RA) – Decision Tree





Risk Assessment (RA) – Decision Tree





Example 1: Synthetic yeast genome

Aim:

Redesign of yeast genome while wildtype phenotype is maintained:

- deletion of repeats and introns
- TAG- > TAA change in stopcodons
- relocation of tRNA genes
- inclusion of loxP sites and PCRtags



To date: 6 chromosomes constructed in individual strains

Next: synthetic genome of a pathogenic yeast. Current RA applicable?



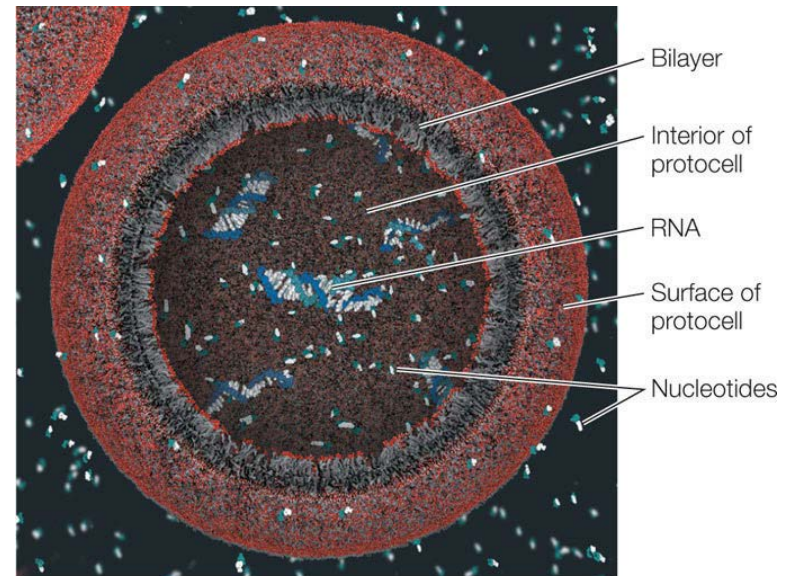
Example 2: Protocells

State of the art:

Artificial cell to mimic one or more fundamental cell biological functions.

Next step:

Artificial cell able to replicate;
current RA method applicable?



4.19: Courtesy of Janet Iwasa, Szostak group, MGH/Harvard.



Example 3: Microalgae in confined systems

