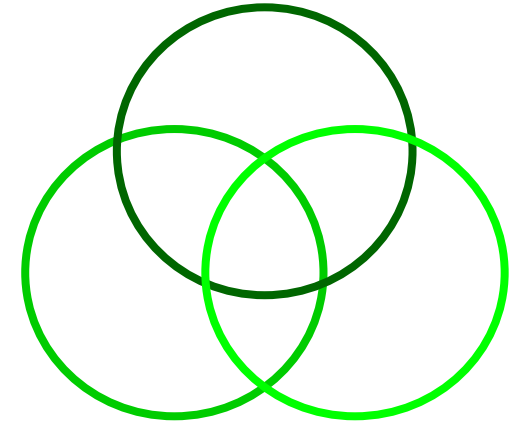
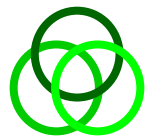


***Biorisk Management***  
***Awareness, Responsibility***  
***and Codes of Conduct***



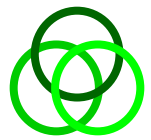
**Success in Biotechnology**  
**through**  
**Science, Safety and Security**



# Strengthening Biosafety, Biosecurity and Biorisk Management

- Raise awareness of dual-use issues in the context of promoting biosafety and bioethics;
- Develop training programs and organize appropriate knowledge transfer in biosafety and biosecurity;
- Establish specific functions and responsibilities with respect to the development of biorisk management in institutions (biosafety professionals);
- Recognize standardization and certification against a biorisk management standard as a major driving force of international implementation of biorisk management programs; and
- Support biosafety organizations in their role in advocating and assisting with the local development of biosafety and biosecurity practices.

Philippe Stroot & Ursula Jenal (2011): A NEW APPROACH, The Nonproliferation Review, 18:3, 545-555, <http://dx.doi.org/10.1080/10736700.2011.618656>



# Omnipresence of Natural Biological Agents

## ***Epidemiology***

- 16% of death are caused by infectious diseases



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## ***Environment***

- *plant and animal pests*
- *invasive species*

- Global trade
- Global warming



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## ***Biotechnology***

- *research*
- *diagnostics*
- *production*

- Advancement of science and technology
- Dual use potential

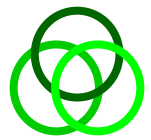


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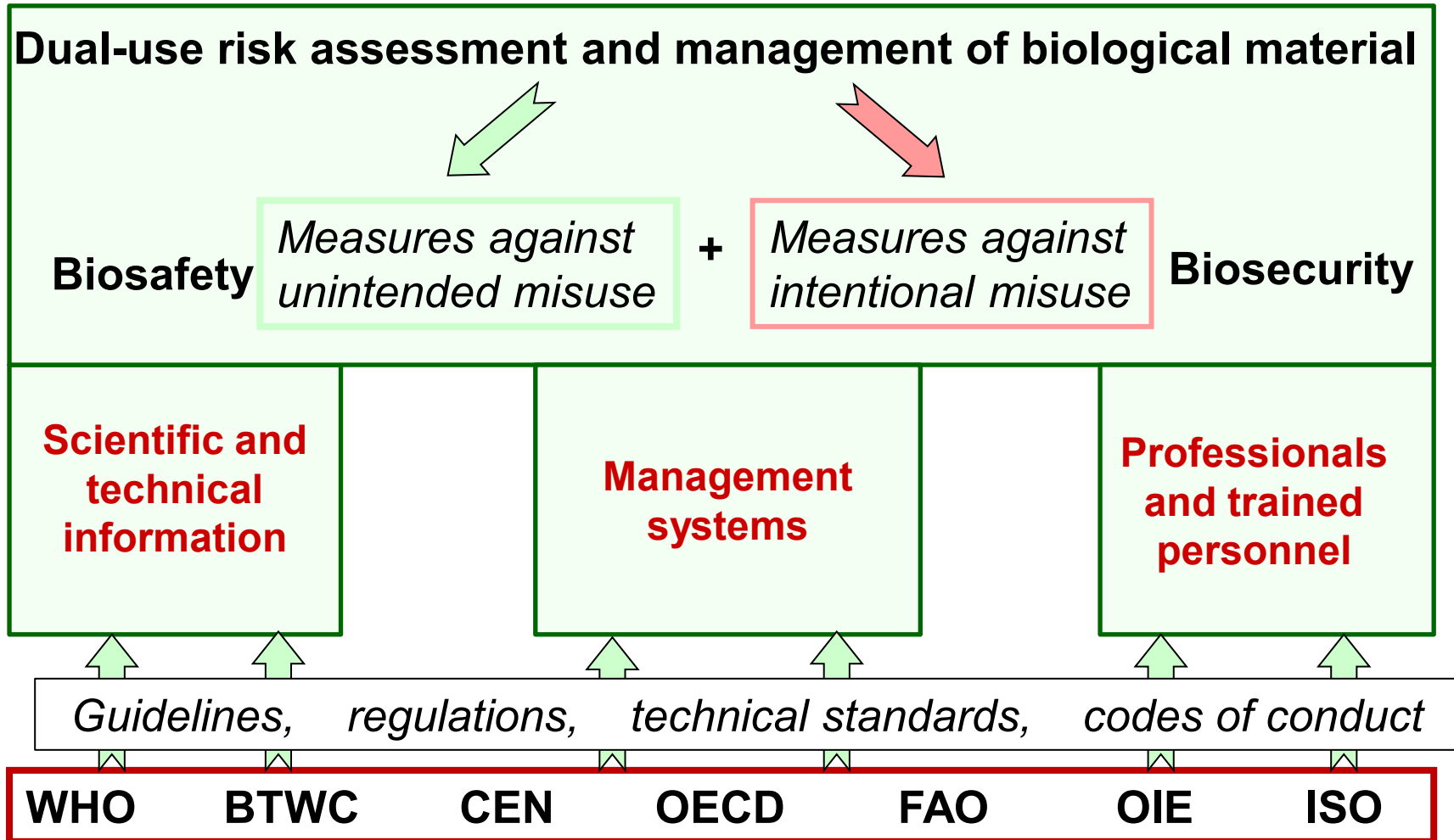
## ***Bioterrorism*** ***Bio-warfare***

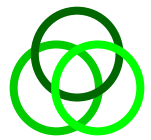
- < 1% of death have been caused by bioterrorist attacks, but huge potential





# The 3 Pillars of Biorisk Management





# International Standards

## Scientific and technical guidance for biorisk management

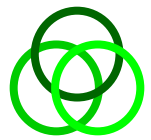
- WHO biosafety manual and laboratory biosecurity guidance and many other specific technical guidance documents

## Guidance on designing a biorisk management system

- CEN Workshop Agreement CWA15793:2011, Laboratory Biorisk Management
- CEN Workshop Agreement CWA16393:2012, Guidelines for the Implementation of CWA15793:2011

## Guidance on competence training for biorisk management professionals

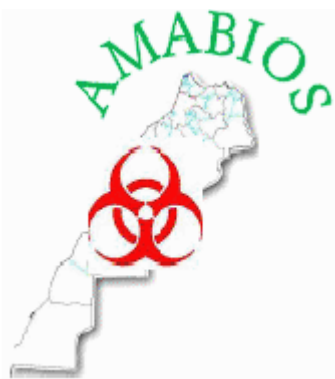
- CEN Workshop Agreement CWA16335:2008, Biosafety Professional (BSP) Competence



# International Standards

- Discrepancies related to the status of biosafety and biosecurity regulation between regions of the world
- Strong interest in international standards to counteract regional regulatory uncertainty.
- Biorisk management to cover biosafety first with subsequent integration of biosecurity.
- Variation between effective programs and very limited programs in academia, the public sectors as well as in smaller private companies.
- International companies with harmonized programs





# Biosafety Associations

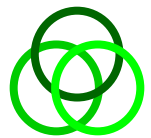


International Federation of Biosafety Associations

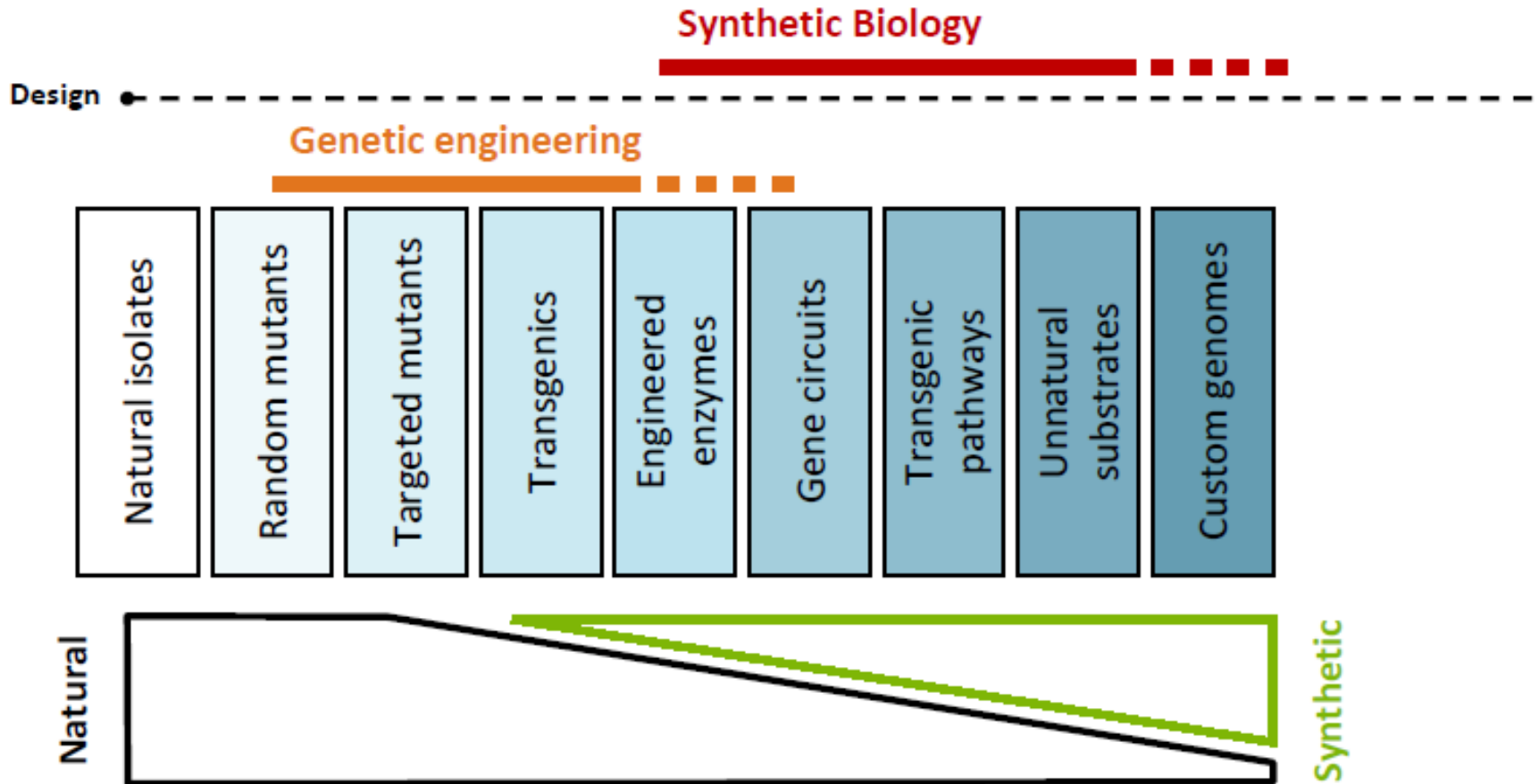
Argentina  
Afghanistan  
Asia Pacific  
Australia & New Zealand



Africa  
Bangladesh  
Brasil  
Cameroon  
Cote d'Ivoire  
Central Asia and Caucasus  
Egypt  
Georgia  
India  
Indonesia  
Japan  
Kenia  
Korea  
Malaysia  
Marco  
Mexico  
Pakistan  
Philippines  
Singapore  
South Africa  
Taiwan  
Thailand  
USA



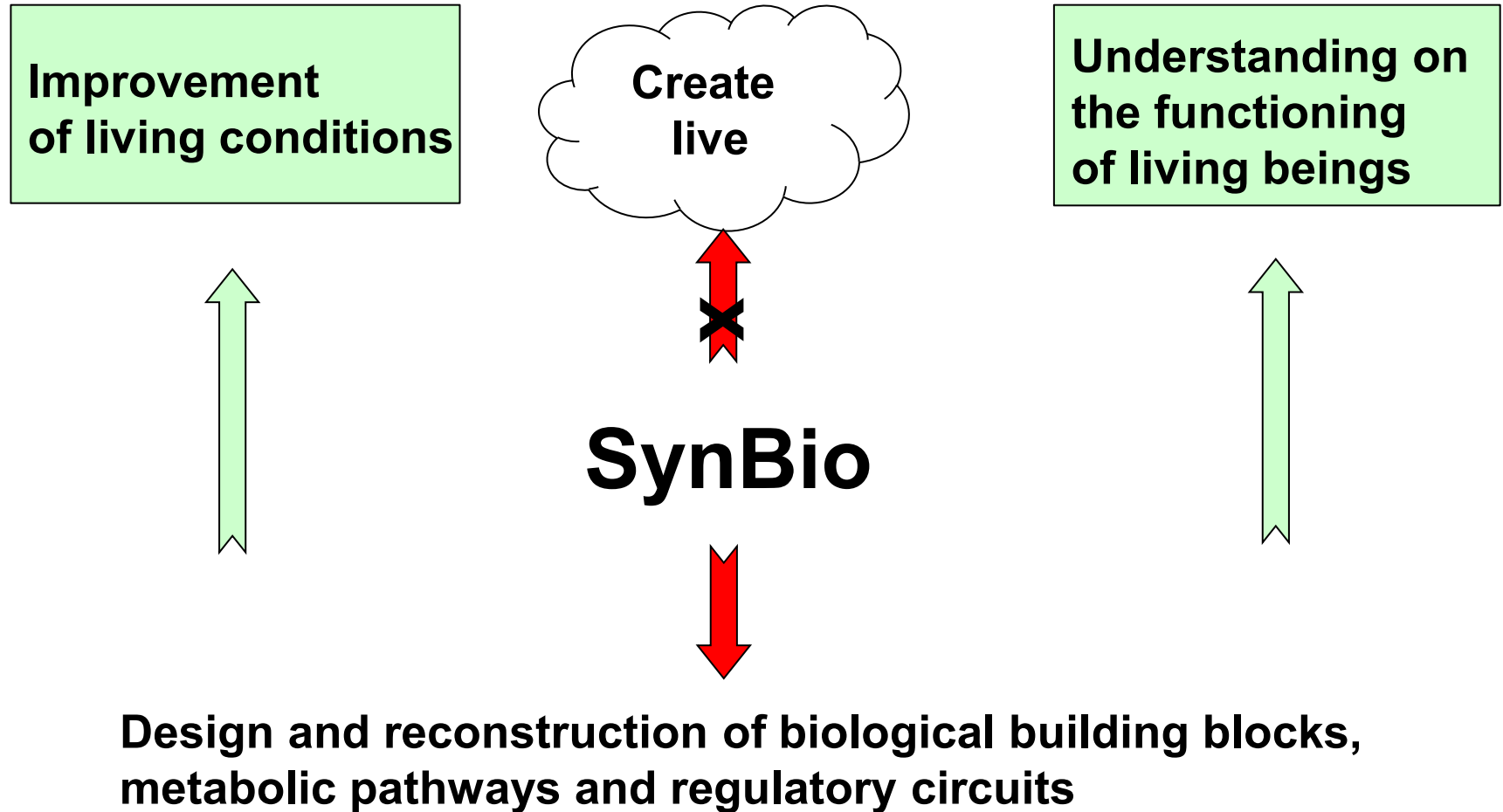
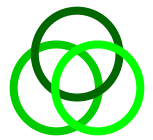
# Synthetic Biology, Advancement of Science

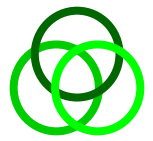


adapted from de Lorenzo (2010) **Bioessays**  
10.1002/bies.201000099



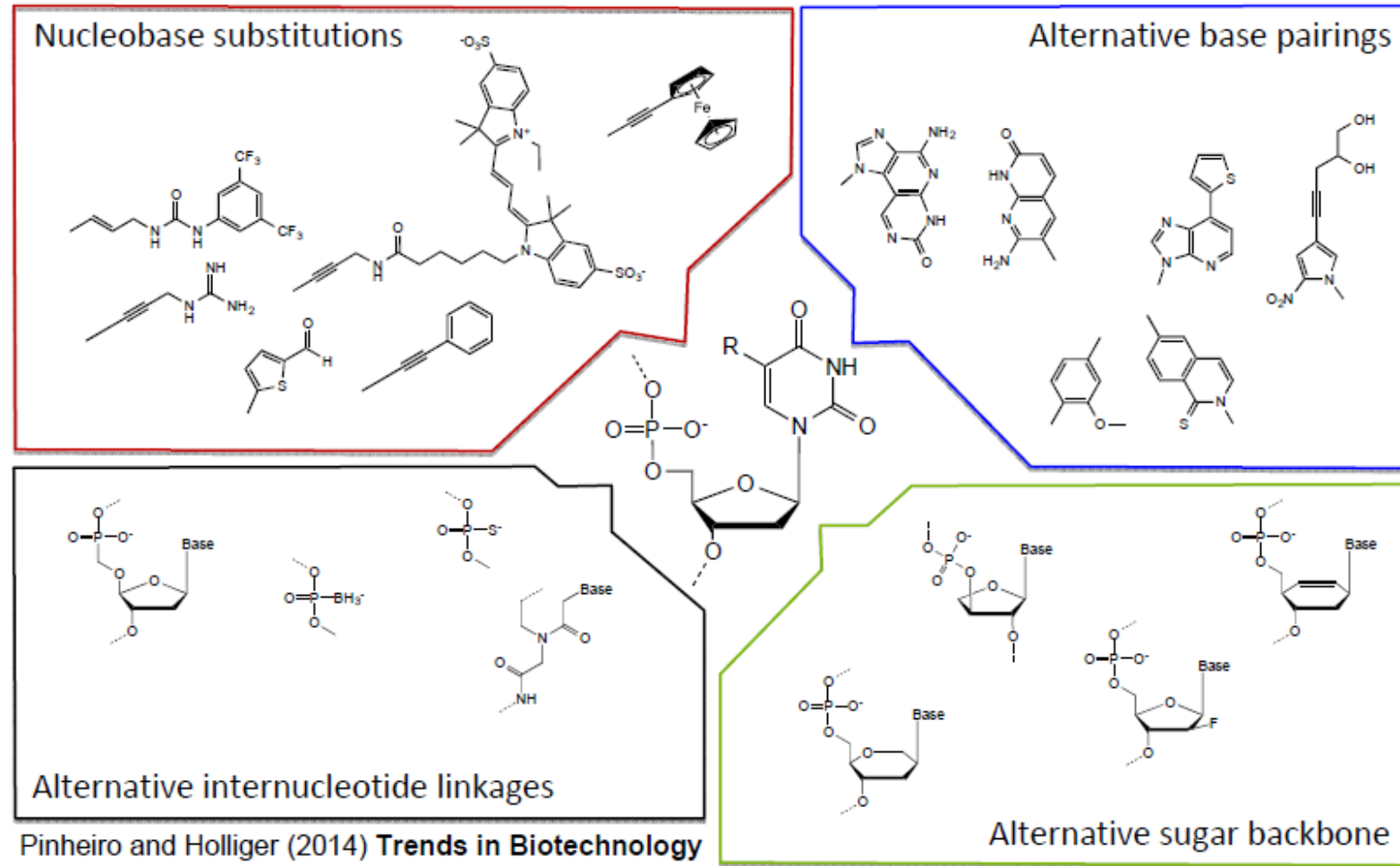
# Synthetic Biology

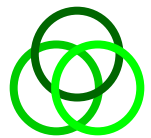




# Synthetic Biology

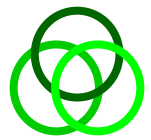
## XNA – Alternative Nucleic Acids



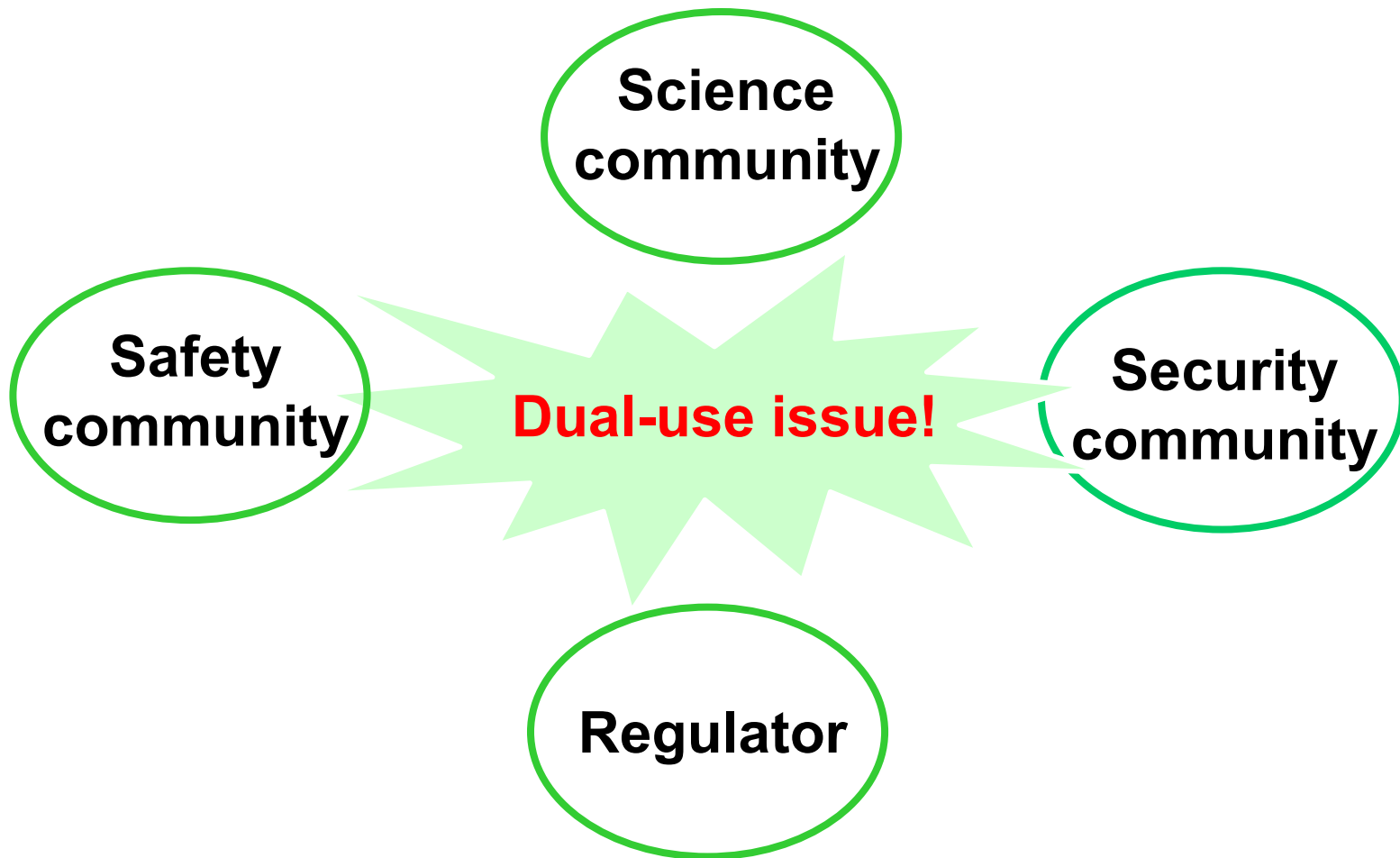


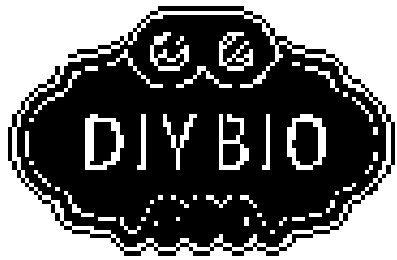
# Synthetic Biology, Proposal for Regulation and Code of Conduct

- **Biosafety**
  - GMO regulation adequate as long as SynBio remains an extension of genetic engineering,
  - Re-consideration in case of significant advances in modifying the basic chemistry of DNA/RNA,
  - Synthetic organism with novel nucleotides (XNA): adopt high safety requirements.
- **Biosecurity**
  - Global code of conduct for DNA sequences screening, customer screening
  - International database of DNA sequence and function: act on suspicious requests
  - Construct institutional codes of conduct.
- **Open information and intellectual property rights**
  - Examine alternative models for owning and sharing information

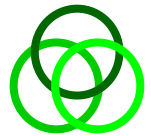


# Continued Need for a Dialogue!

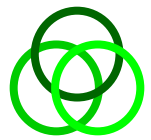




# Do It Yourself Code of Ethics



- **Transparency:** Emphasize transparency and the sharing of ideas, knowledge, data and results.
- **Safety:** Adopt safe practices.
- **Open Access:** Promote citizen science and decentralized access to biotechnology.
- **Education:** Help educate the public about biotechnology, its benefits and implications.
- **Modesty:** Know you don't know everything.
- **Community:** Carefully listen to any concerns and questions and respond honestly.
- **Peaceful Purposes:** Biotechnology must only be used for peaceful purposes.
- **Respect:** Respect humans and all living systems.
- **Responsibility:** Recognize the complexity and dynamics of living systems and our responsibility towards them.
- **Accountability:** Remain accountable for your actions and for upholding this code.



# Outlook and the New Generation

- Involvement of young people supports awareness raising in biosafety and biosecurity
- Involvement of young people's creativity and capability is paramount not only for science but for the society at large

