Synthetic biology: a view from SCENIHR

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Safety, health and environment of SB products

- The role of the SCENIHR
- A risk assessment framework for SB products
- Other requirements

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The role of SCENIHR in the EU

To provide independent, expert advice to the Commission Services on the health effects and related impacts of:

- Emerging issues including new technologies
- Various medical devices
- Other issues requiring a multidisciplinary risk assessment
- Risk assessment methodology

Examples of current risk assessments by the SCENIHR

- Nanotechnologies
- Biocides and antibiotic resistance
- Electromagnetic fields
- Energy saving light bulbs
- Reprocessing of single use medical devices
- Addictive substances in tobacco

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Synthetic biology (SB): Some parallels with SCENIHR's work on risks from nanotechnologies

- Rapidly changing data base
- Great range of potential applications from health care and environmental remediation to textiles and fuel cells.
- Very limited information on health and environmental aspects

Requirements for a risk assessment of an SB product

i) Characterisation of the relevant physical and chemical properties of each product/ process along with information on biological properties

ii) Assessment of the potential exposure of humans, animals and the environment under expected and misuse conditions

iii) Examination of the hazardous properties

iv) Estimation of the risk

Human exposure (life cycle)

- Exposure during research and development
- Exposure of workers during manufacture
- Exposure of consumers and/or other users
- Exposure of workers and others during inactivation/disposal/re-use

Human exposure situations

- Containment effective therefore no exposure
- Some exposure will occur but it is unlikely that the SB product will be absorbed
- Absorption will occur but likely to be limited with rapid clearance
- Absorption will occur and the SB product or a ‘metabolite’ may persist in the body

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Environmental exposure situations

- No environmental release
- Release in very local areas only
- Widespread release but rapid degradation
- Widespread release and persistence.

Assessment of the hazardous properties

There is no reason to assume that SB products will have common hazardous properties. Consequently, for the foreseeable future, each one will have to be considered separately (i.e. a case by case basis as for products of nanotechnologies)

Risk Assessment categorisation?

- Conventional risk assessment for defined chemicals/materials (1A, *Known substances and 1B, substitutes for existing chemicals/ materials*)
- Conventional risk assessment approach for microorganisms/ GMO's ? *(2, Modified organisms)*
- New approach needed ? (3, *Novel organisms/ combinations of organisms)*
- New approach needed? (4, *unknown*)

Ensuring SHE without unnecessary inhibition of SB development

- Research on SHE aspects must be properly funded and integrated
- Development of common working definitions, data reporting protocols and codes of practice
- Implementation of effective and sustainable procedures for early provision of all relevant information to the risk assessors along with frequent stakeholder discussions.
- Identification of essential information to estimate the risks
- The development of a common framework for considering risks and benefits

Avoiding past mistakes

Safety, health and environment should not be an add-on (after thought) rather they must be an integral part of design, development and industrialisation and take into account the full life cycle including scenarios of misuse.

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