
GOVERNANCE APPROACHES FOR HUMAN GENE EDITING BASED ON RESPONSIBLE RESEARCH AND INNOVATION

International Summit on Human Gene Editing
December 1-3, 2015, Washington D.C.

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Rational

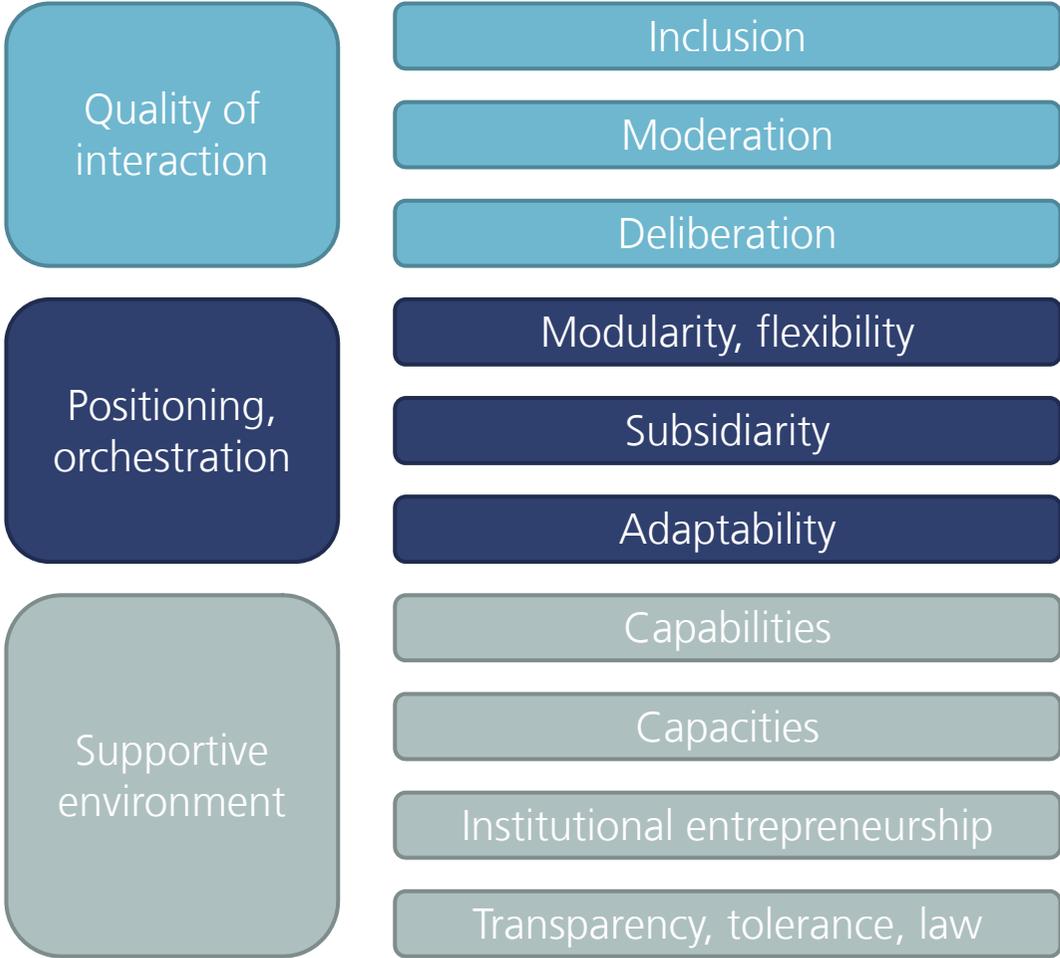
- Human gene editing: simple, rapid, high impact
- Implications for **governance** approaches:
 - **Simple:** in operation asap
 - **Rapid:** anticipatory and adaptive
 - **High impact:** grounded on societal acceptability, considering all relevant stakeholders

Responsibilization

- Societal stakeholders and innovators share mutual responsibility for innovation with respect to acceptance, sustainability, impact and consequences.
- Innovation becomes embedded deeply into societal structures.
- Reflexive, self-organized and collective design and operation of governance instruments.
- Responsibilization
 - means internalization of issues of concern and represents a fundamental transformation of the innovation system;
 - goes far beyond initiating a public debate or engaging with various stakeholders and discussing gene editing issues.

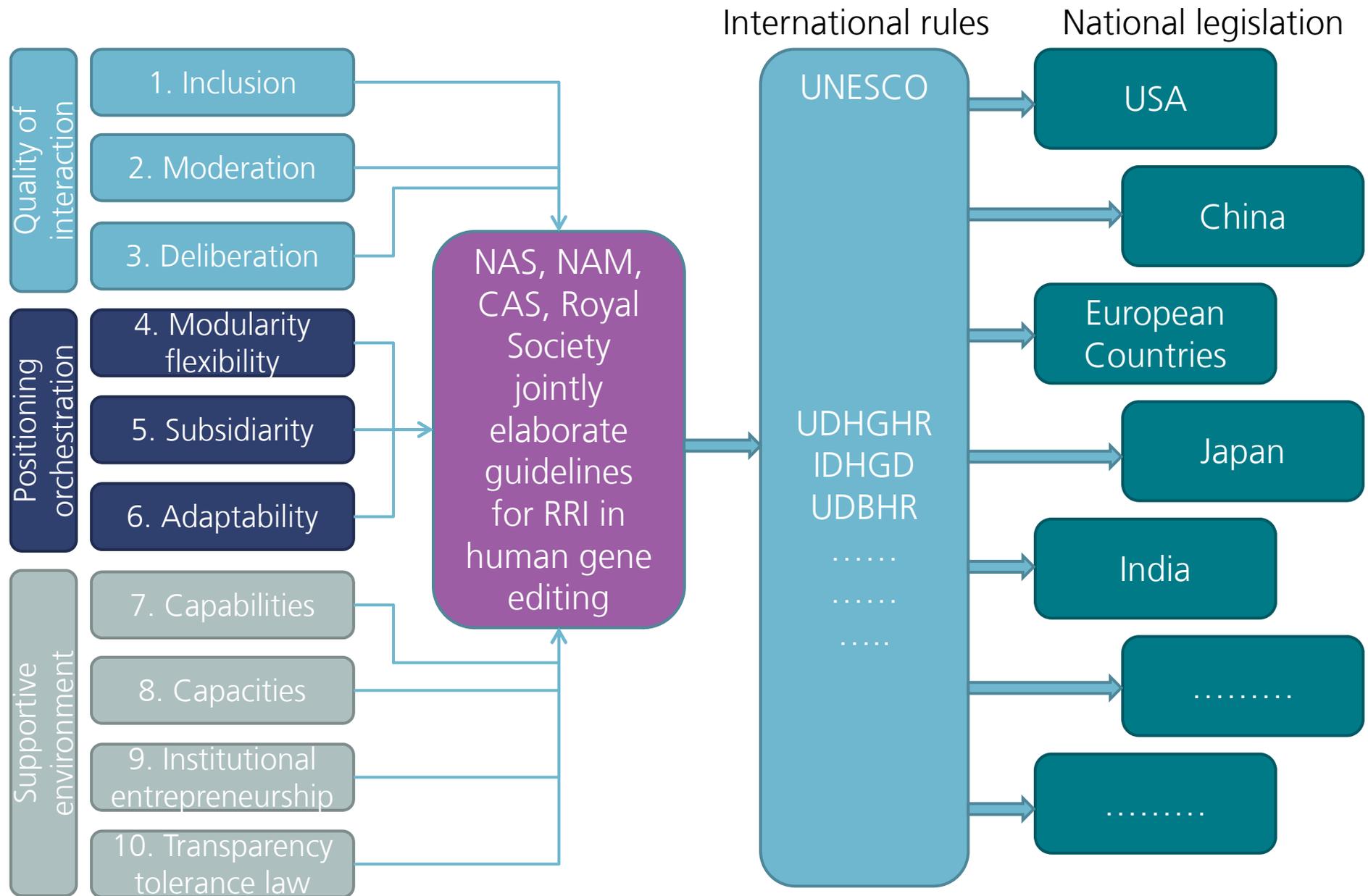
Source: Res-AgorA-project <http://res-agera.eu>

10 governance principles towards responsabilization



Source: Res-AgorA-project <http://res-agora.eu>

Responsibilization of human gene editing



Responsibilization of human gene editing: A first step? (1)

NAS, NAM, CAS, Royal Society jointly elaborate **guidelines** for RRI in gene editing as a basis for international rules and national legislation

- **Design of process:**

- Establish independent and highly credible moderator, e.g. IBC (p2)
- Assure legitimation of process (p1)
- Involve all relevant stakeholders and double check relevance for the issue (p1)
- Make transparent interest, motives and values of stakeholder (p1)
- Discuss and decide about methods and procedures (p1): workshop series, online consultation, surveys

Responsibilization of human gene editing: A first step? (2)

- **Execution of process**

- Jointly define scope and goals (p1):
 - focus on medical applications of gene editing
 - geographical coverage (US, CN, EU)
- Develop rules to be applied within funding of each organization (p7, p8) (short term) and to form basis for international rules at the UNESCO level (mid term)
- Identify issues and required evidence base (p3)
- Make transparent different knowledge base of involved stakeholders (p10)
- Fact finding: governance settings in place globally, structure into hard and soft and mixed forms, ongoing debates, key insights
- Formulation of guidelines

Conclusions

- Urgent need for governance approaches and instruments
- Governance of human gene editing needs to be
 - Anticipatory and adaptive
 - Broadly grounded on societal acceptability considering all relevant stakeholders
- RRI-framework offers principles and guidelines facilitating the development of such governance instruments
- Joint development of guidelines for RRI in human gene editing by hosts of this summit as first step?
- Shared responsibility between all relevant stakeholders as key issue