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CRISPR-Cas9 research in ERCEA Ethics Process

Filipa Ferraz de Oliveira
ERCEA Scientific Officer

Fostering Responsible Research With CRISPR-Cas9, Paris, March 2016

CRISPR-Cas9 research in ERCEA Ethics Process



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1. Introduction: CRISPR-Cas9 in the EC ethics review

- i. Ethics review process in ERCEA
- ii. Research with hESC – ethics process
- iii. CRISPR-Cas9 ethics recommendation

2. CRISPR-Cas9 ethics issues

- i. Reshaping animals
- ii. Engineering plants
- iii. Human genetic therapy
- iv. Environmental release
- v. Misuse

3. CRISPR-Cas9 in ERC research projects

- i. Some quantitative information



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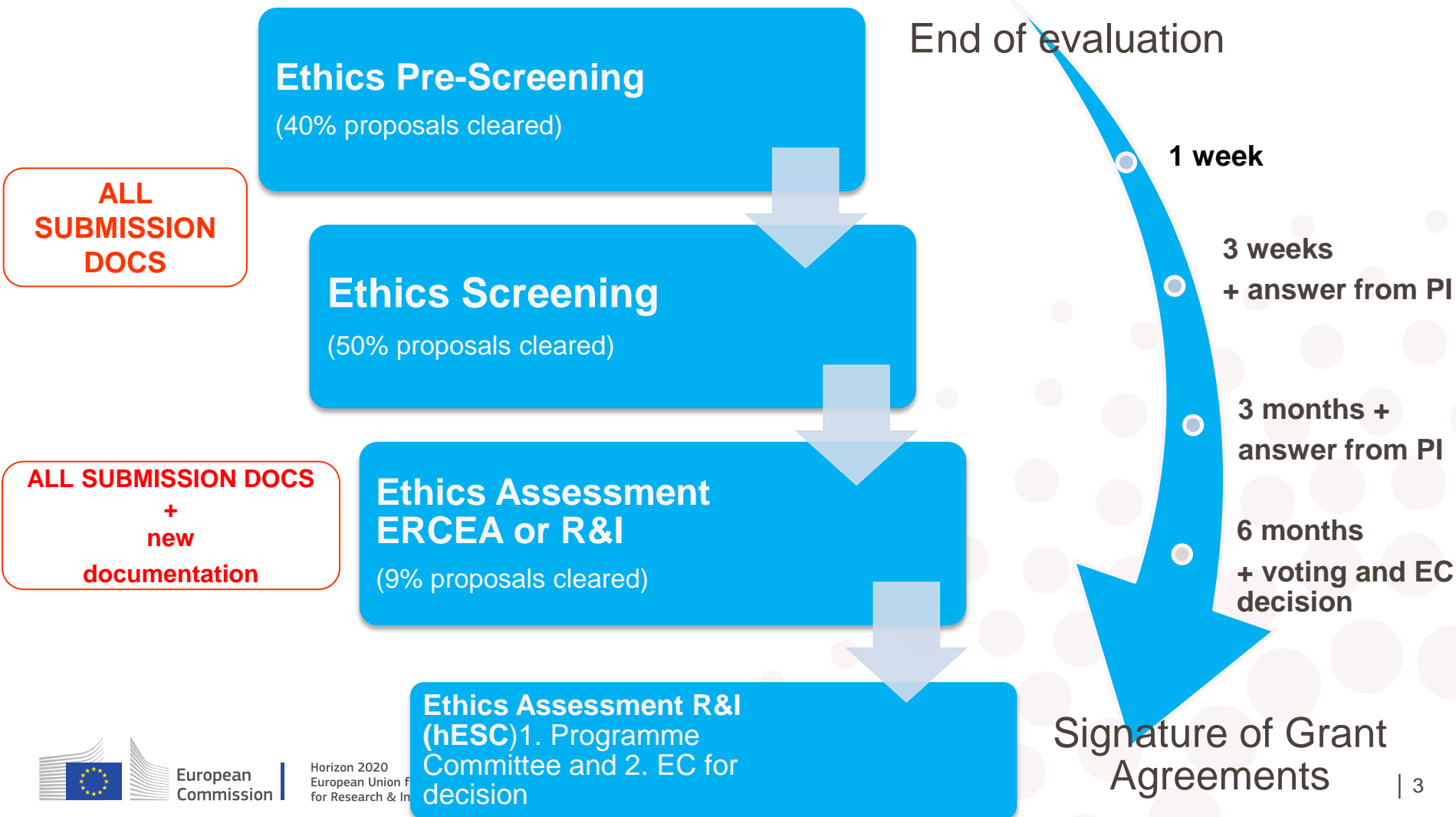
Horizon 2020
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CRISPR-Cas9 in EC ethics review



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Ethics review process in ERCEA



CRISPR-Cas9 in EC ethics review

Research with hESC – ethics process



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When...

1. The proposal has all ethics documentation needed and
2. **Project** and **cell lines** are registered at **Human Pluripotent Stem Cell Registry** (hPSCreg)

The proposal is sent to:

1. Programme **Committee** (representatives of all Member States) votes for approval of funding
2. After the voting of the Committee the **European Commission** should adopt a **decision**

CRISPR-Cas9 in EC ethics review

Research with hESC – ethics process



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Cannot be financed under Horizon 2020:

- research activities aiming at **human cloning** for reproductive purposes
- research activity intended to **modify the genetics of human beings** that could make such **changes heritable**
- research activities intended to **create human embryos** solely for the purpose of research or for the purpose of **stem cell procurement**, including by means of somatic cell nuclear transfer.

CRISPR-Cas9 in EC ethics review

CRISPR-Cas9 ethics recommendation



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CRISPR-Cas9 research in ERCEA

Ethics Process



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CRISPR-Cas9 ethics issues

Reshaping animals

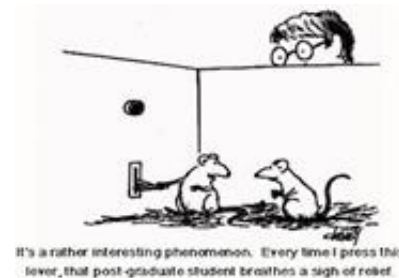


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Gene editing experiments producing genetic modified creatures as:

- Flies, mosquitos, worms capable of resisting the transmission of certain diseases
- Mice and extra muscular ferrets
- Cows without horns



- **Animal protection**
(Directive 2010/63/EU of the European Parliament)
- **GMO production**
(GMO Directive 2009/41/EC)

CRISPR-Cas9 ethics issues

Engineering plants



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Gene editing experiments producing genetic modified plants as:

- Gene-edited potato
- Corn resistant to weed killers



- **GMO production**
(*GMO Directive 2009/41/EC and the Cartagena Protocol on Biosafety*)

CRISPR-Cas9 ethics issues

Human genetic therapy

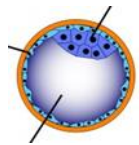


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Gene editing experiments with human cells

- Gene therapy in adults or children
- Editing genes in



human embryonic stem cells



- **hESC compliance with EU and national law**
(Statement of the Commission related to research activities involving human embryonic stem cells)
- **Human cells and tissues in general**
(EU Directive 2004/23/EC)

CRISPR-Cas9 ethics issues

Environmental release



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"Gene drive" technology or installing gene-editing machinery in a living being

- Mosquitoes resisting malaria and capable to reproduce
- Environmental changes hard to undo



- **Precautionary principle and the legislation on nature conservation and pollution control**

(Cartagena Protocol on Biosafety)

Misuse

Gene editing experiments allowing the production of dangerous bio-elements

- Easy accessible technology – low price
- Uncontrolled experiments



- **Research that has other potential for terrorist or criminal abuse**
(Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction)

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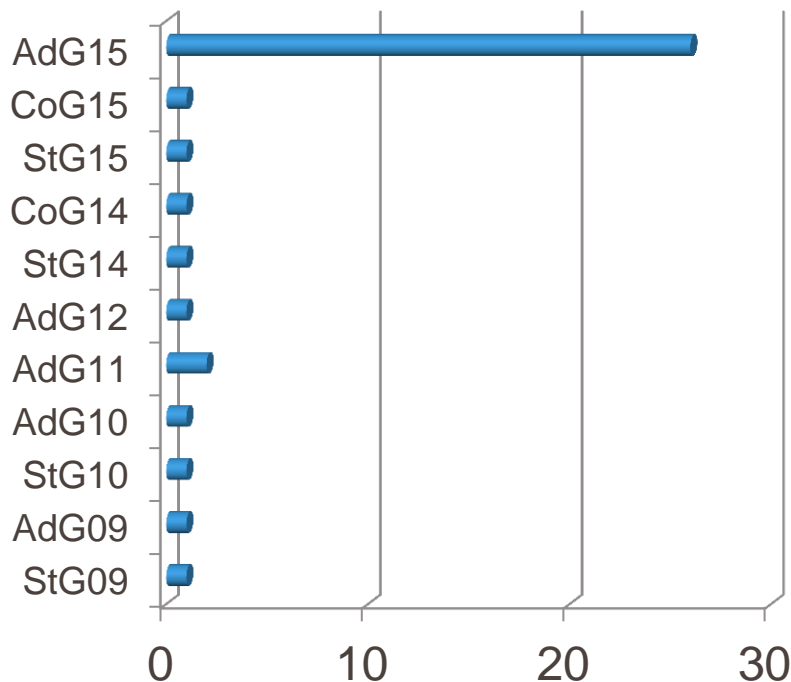
CRISPR-Cas9 in ERC research projects



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CRISPR-CAS Funded projects in ERCEA



- Projects referring Tandem repeats and/or CRISPR-Cas technology being used
- First project using CRISPR-Cas in StG14
- In AdG15 all 26 projects refer to the use of CRISPR technology

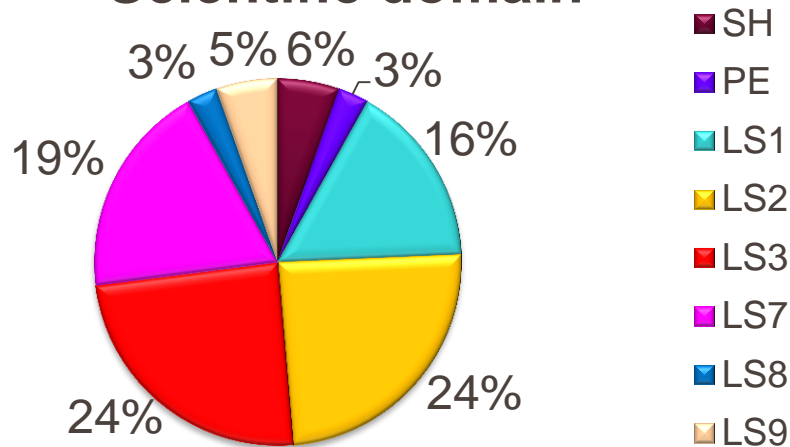
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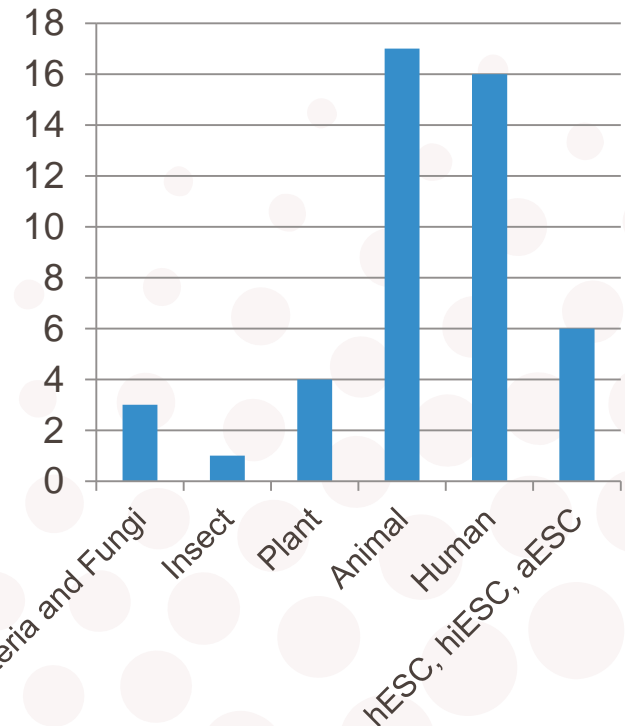
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Scientific domain



- LS1 - Molecular and Structural Biology and Biochemistry
- LS2 - Genetics, Genomics, Bioinformatics and Systems Biology
- LS3 - Cellular and Developmental Biology
- LS7 - Diagnostic Tools, Therapies and Public Health
- LS8 - Evolutionary, Population and Environmental Biology
- LS9 - Applied Life Sciences and Non-Medical Biotechnology

Type of cell involved



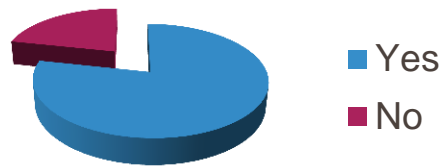
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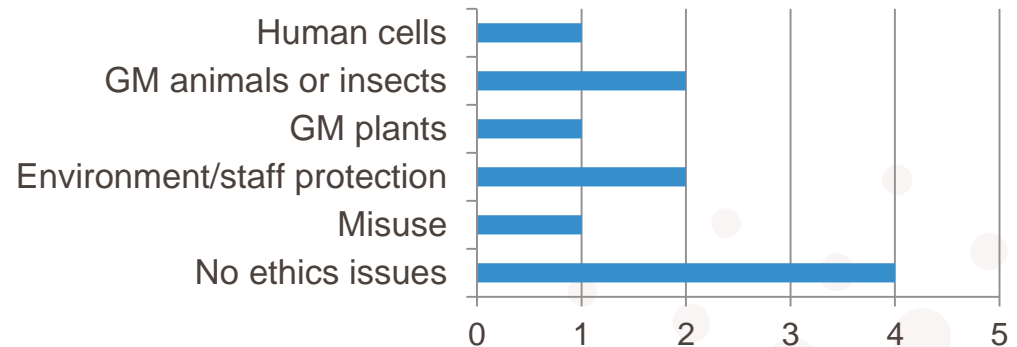
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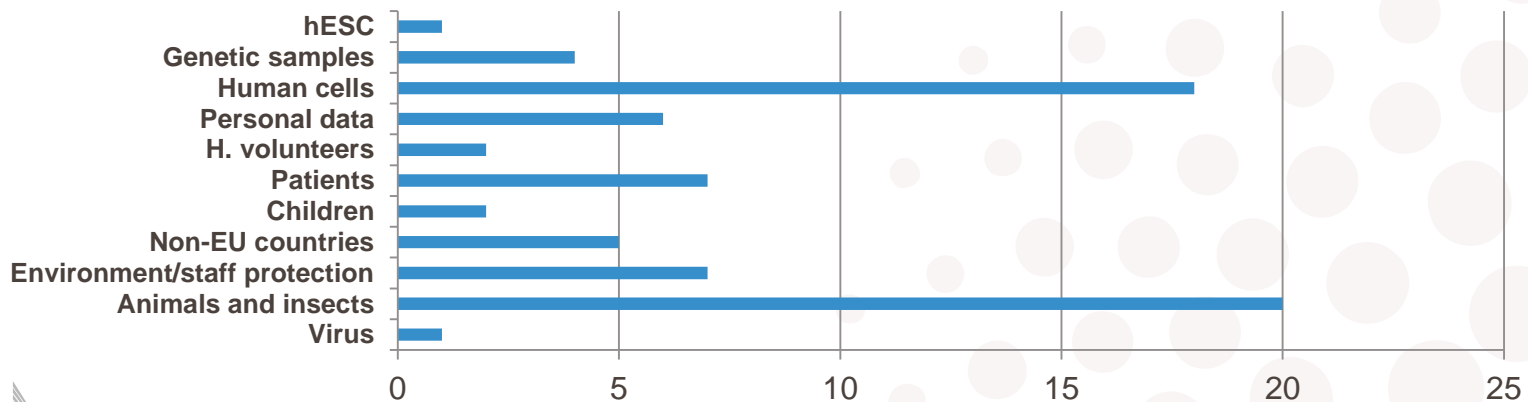
Projects with ethics issues flagged by the PI



Ethics issues found in the "not flagged" projects



Ethics issues found in the "flagged" projects





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THANK YOU...

QUESTIONS?