

Gene therapy ATMPs:
HCB's scientific committee expertise
for contained use and deliberate
release

High Council for the biotechnology : who are we ?

HCB A PUBLIC ORGANISM FOR BIOTECHNOLOGY ASSESSMENT

- HCB: French independent body
- Launched: April 2009.
- HCB is built to provide comprehensive and evidence-based guidance for public policy-making on issues relating to biotechnologies, including GMOs.
- Assesses the potential risks to the environment and public health associated with GMOs, as well as their social and economic impact.
- **Systematically** consulted by the French CA for all GMO dossiers involving GM microorganisms, plants or animals,
 - **for contained use or deliberate release,**
 - for research, development, education, or commercial purposes,
 - in the fields of agriculture, **health**, food and feed, energy, research and the environment.

HCB AN ORIGINAL STRUCTURE IN THE EUROPEAN LANDSCAPE (1/2)

- Unlike 'conventional' assessment bodies, HCB is combining a Scientific Committee and an Economic, Ethical and Social Committee.
- With the two committees the positions of the various stakeholders, while being fully considered, do not interfere with the scientist's analysis.
- Accordingly the system allows scientists in all biological fields, social scientists and stakeholders to push relevant questions to each other.

HCB AN ORIGINAL STRUCTURE IN THE EUROPEAN LANDSCAPE (2/2)

Scientific Committee

Composition (40 members) :

- research scientists expert in the fields of **genetics**, molecular biology, microbiology, **human** and animal **health protection (medical research**, veterinary science, toxicology, epidemiology, allergy, pharmacology, **virology**, **gene therapy**...), agricultural science, environmental science and statistics.

Role:

To provide science-based analysis of the **potential risks to the environment and public health** associated with any biotechnology.

Remit:

Includes GMO applications for **contained use and deliberate release**.

Output: Scientific opinion.

Economic, ethical and social Committee

Composition (35 members) :

- stakeholders relevant to HCB mandate (consumer groups, professional organisations in farming, agribiotech, pharmaceuticals, NGOs for the protection of the environment, etc),
- broader representatives of civil society (mayors, departments, regions, members of parliament and senate), and
- members qualified in sociology, economics and law.

Role:

To provide an analysis of the impacts of biotechnologies with respect to social, economic and ethical issues.

Remit:

Includes GMO applications for **deliberate release only**, not for contained use.

Output: Recommendation.

HCB Opinion

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graph TD; A[Scientific opinion.] --> C[HCB Opinion]; B[Recommendation.] --> C;
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Practical aspects and methodology leading to
HCB's approval of GT ATMPs:
A two steps process

HCB CONTRIBUTES TO BOTH STEPS

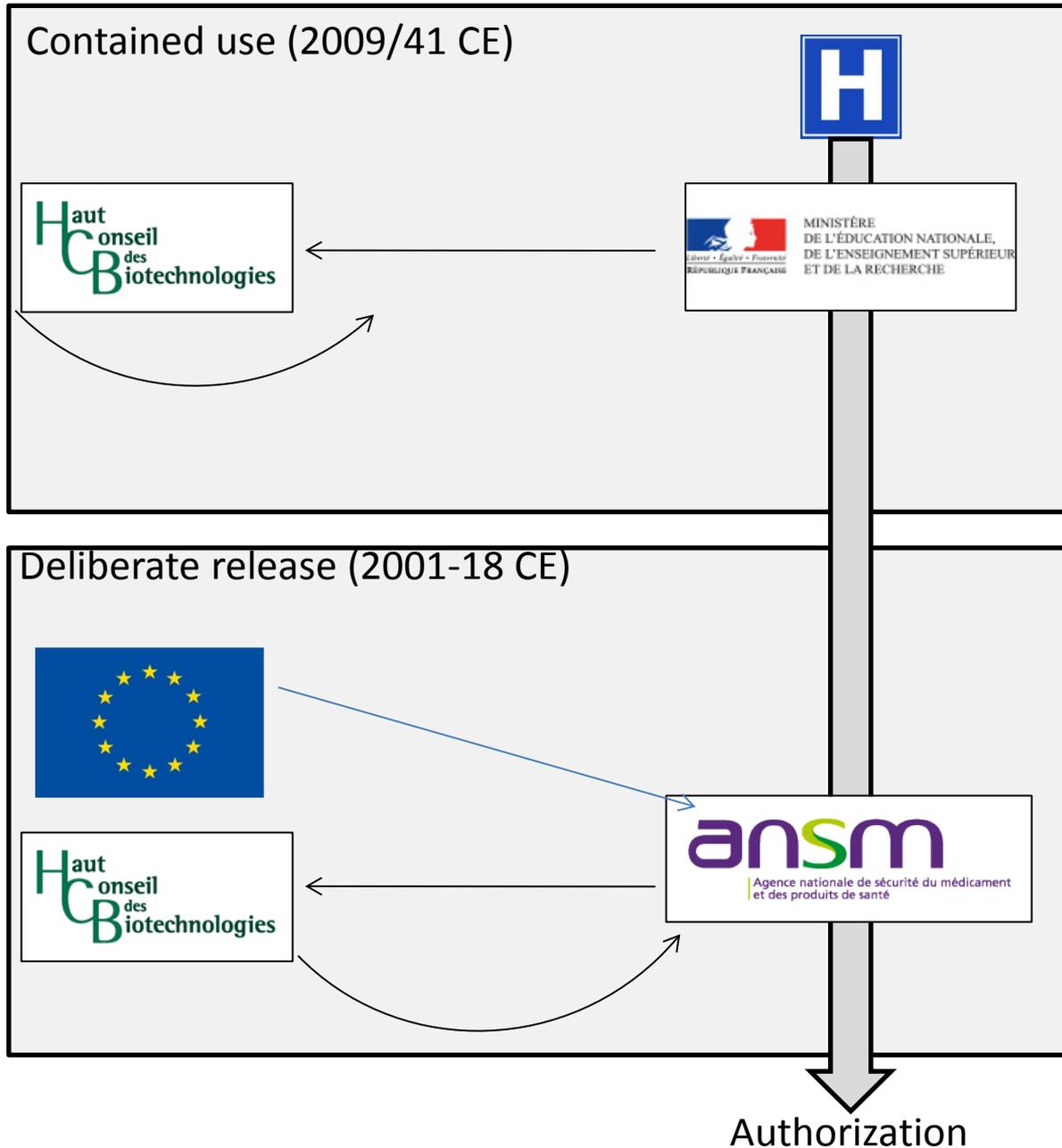
The High council for biotechnology is involved in the contained-use evaluation.

- The HCB is systematically involved in a first step of the evaluation process: the analysis addresses:
 - The type of facilities needed to produce and manipulate the ATMP, with a special focus on the clinical use: practitioners, nurse or physician manipulation of the product and patient housing.
 - The HCB also gives an opinion and an evaluation of the risk of release from the patient.

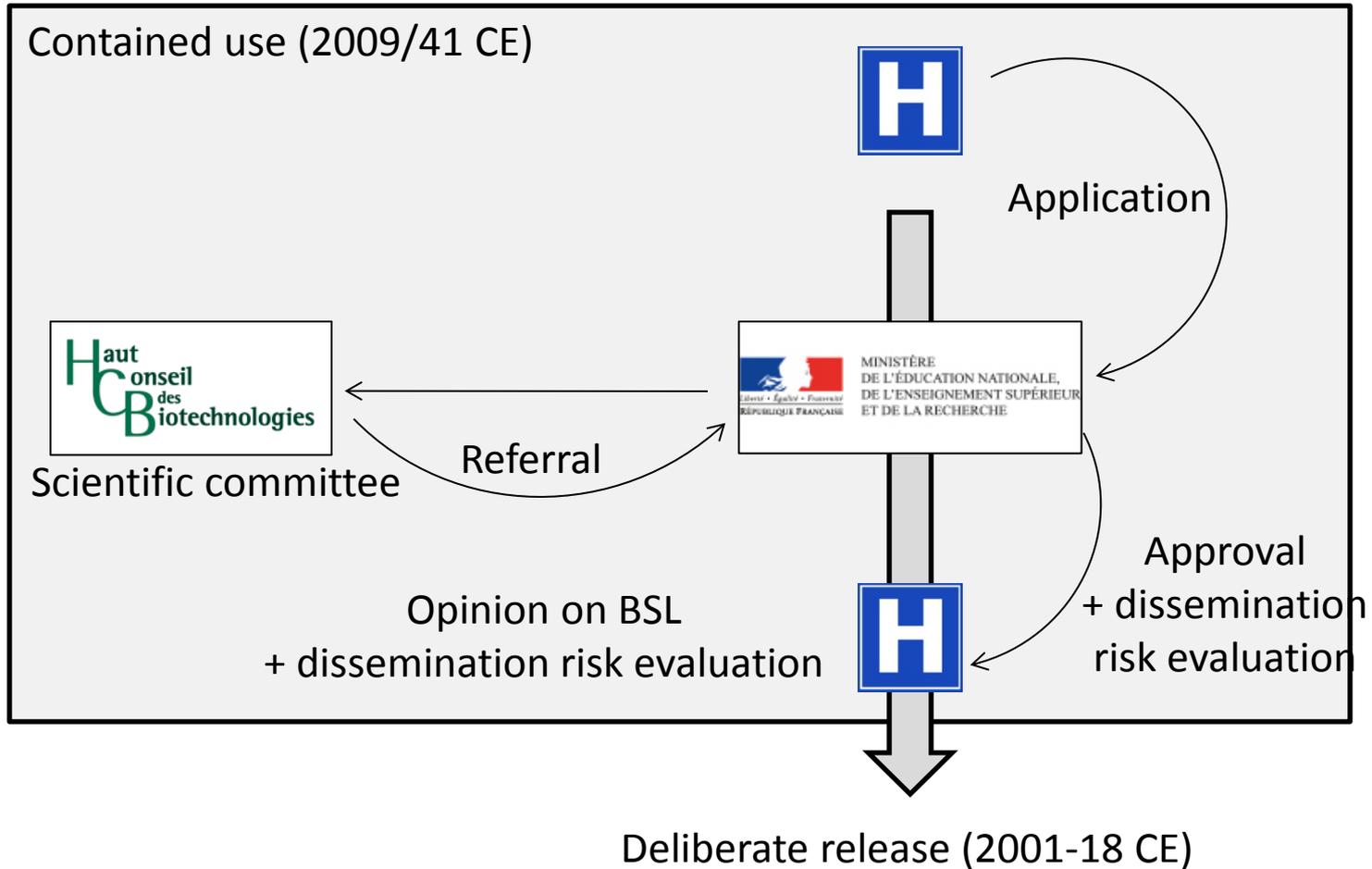
According to the latter analysis (Y/N), the HCB can be involved in the deliberate release evaluation:

- HCB is activated if a deliberate release exists.
- During this second step, both the EESC and the SC are contributing.

GENERAL PROCEDURE



CONTAINED USE STEPS

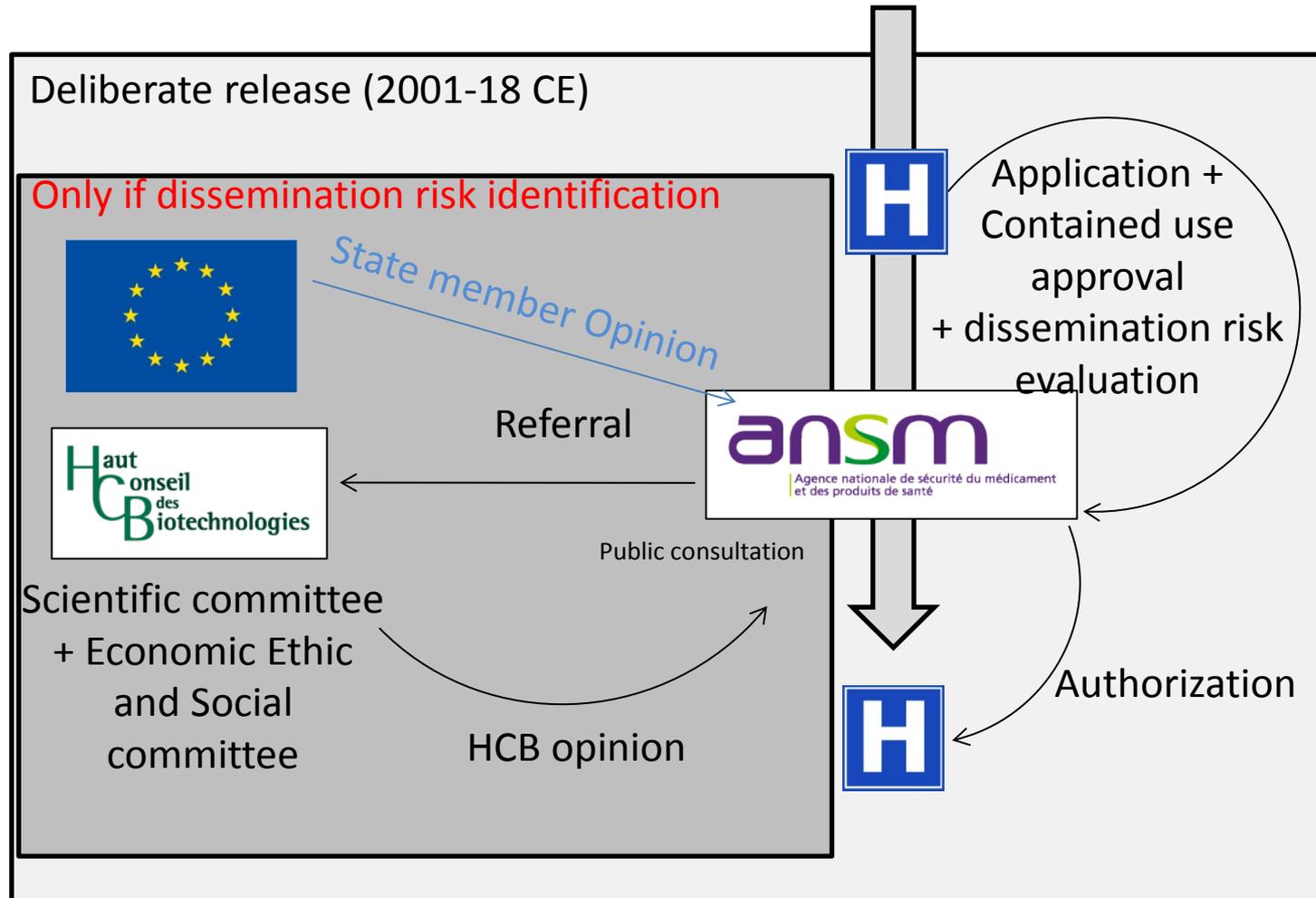


HOW DOES HCB CONCLUDES FOR THE RISK OF DELIBERATE RELEASE ?

- HCB scientific committee identifies a risk of deliberate release when biological data suggests the presence, in biological fluids (including cutaneous lesions p.e.), of a potential replicative agent.
- Nevertheless, HCB scientific committee does not consider as a deliberate release, the shedding, in the same fluids, of a defective agent.

DELIBERATE RELEASE

Contained use (2009/41 CE)



Deliberate release (2001-18 CE)

Only if dissemination risk identification



State member Opinion



Referral



Public consultation

Scientific committee
+ Economic Ethic
and Social
committee

HCB opinion

Application +
Contained use
approval
+ dissemination risk
evaluation

Authorization

Thank you