

Ten Suggestions regarding the Integration of the Ethical, Social and Public dimension in the European Biotech Policies

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- Based upon discussions on a report on Ethical principles in European regulation of biotechnology at a workshop within the framework of The Danish Action Plan for Biotechnology and Ethics.

INTRODUCTION

The European Council in March 2002 asked the Commission and the Council to develop measures, which enable Community businesses to exploit the potential of biotechnology while taking due account of the precautionary principle and meeting ethical and social concerns.

The Commission's Communication on a biotechnology strategy and action plan emphasises that a broad public support is essential for a successful development of a competitive biotechnology sector in the EU, and that ethical and societal implications and concerns must be addressed. The Commission further recommends that a number of actions be taken to support the inclusion of societal dialogue and ethical implications.

In that respect the focus is on three various aspects that play a major role for the possibilities for integrating ethical and societal aspects in setting the framework for the development of the biotechnological products and treatment techniques:

- I. Ethical considerations and public participation in research and development activities
- II. Setting the European Ethical Agenda
- III. Ethical and social considerations in approving new applications of biotechnology

These issues were discussed at a workshop in Copenhagen 8/9 October 2002 with representatives from EU member states and the EU Commission. The basis for the workshop was a report on "Ethical principles in European regulation of biotechnology". Based on the discussions of the workshop the following ideas and suggestions could be considered. The main focus is on the EU-level, even if it is acknowledged that some aspects call for international or national approaches.

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I. ETHICAL CONSIDERATIONS AND PUBLIC PARTICIPATION IN RESEARCH AND DEVELOPMENT ACTIVITIES

The BioECONOMY- dimension:

1. Objective: **To promote the scientists' ethical reflections in research and development**

Suggestions: Secure the integration of bioethics and bioscience and promote interdisciplinarity between scientists and establish fora for scientists to meet and have a dialogue with civil society. The ethical aspects in research projects should be dealt with up-front and on an interdisciplinary basis. Education in bioethics at the undergraduate level and continuing education of established scientists should be offered to enable their participation in bioethical discussions. This could be promoted by co-ordination at a European level, respecting that education is a national responsibility. Scientists should also focus on dialogue and maintain a double focus: not only disseminating knowledge from scientists in to the civil society but also embedding the values and perspectives of civil society into science.

2. Objective: **To expand the request for ethical reviews in public funded biotechnological research in order to help public engagement in the work of science**

Suggestions: Applications for public funding of research projects should where relevant contain an ethical assessment as an integrated part of the research projects. The same should be considered to apply to other public funded activities where science includes bioethical aspects.

3. Objective: **To improve methods/tools for the integration of ethical reflection and dialogue in institutes and companies concerning the whole development process from research to marketing**

Suggestions: It is important that there is a method for systematic dialogue between research and society on biotechnology and ethics. This dialogue should address the dilemmas and be based on real cases and. It is important that the public and private research review specific ethical considerations in an open dialogue with stakeholders and society. Biotechnological companies and research institutes should be encouraged to integrate bioethics in other company policies on an equal basis as in public biotech policies. Ethical guidelines and ethical management systems that can help integrate bioethical considerations should be promoted. Such systems could in addition serve as a communication on the bioethical profile to investors.

II. SETTING THE EUROPEAN ETHICAL AGENDA.

The BioDEMOCRACY- and BioETHICAL - dimension

The dialogue

4. **Objective: To promote dialogue between stakeholders on the European level**

Suggestions: “Triologue” consultations between the EU institutions on important issues with regard to biotechnology and ethics should be held between the Commission, the Council and the Parliament. Dialogue between other stakeholders should include science, society, industry, consumers, NGO, authorities and citizens. The framework for such a dialogue between stakeholders should be organised in a neutral and independent way and take place in formalised structures. It is important that purposes, questions and priority of subjects of the discussion are made clear from the outset. It should also be clear who is initiating to the discussions, how the outcome will be fed back to the decision-makers and who should make the decisions on the outcome of the discussions. Professional societies could play an important role in that respect. The dialogue should include reflections on both the possibilities and pitfalls of biotechnology. The dialogue should take place both at a European level and at a national level.

The Ethical Considerations

5. **Objective: To make a set of fundamental ethical considerations on which there would be general consensus between member states to be taken into account when taking decisions in the field of biotechnology**

Suggestions: Promote a discussion in the European Group on Ethics of fundamental ethical principles and their underlying values on which there could be general consensus between Member States based on the Charter of Fundamental Rights as a model for EU aspiration. This should be carried out in collaboration with ethical bodies at the EU level and in member states and should involve stakeholders as mentioned in suggestion 4. Such fundamental ethical principles should be taken into account when making decisions in the field of biotechnology keeping in mind the limited competence in the existing EU-regulation to integrate ethical considerations.

Ethical advice:

6. Objective: **To strengthen the role of ethical advice**

Suggestions: It is important that the activities of different ethical bodies both nationally and internationally should be closely co-ordinated taking into account existing networks in this respect. It should be considered whether the dialogue between ethical bodies and the civil society is sufficiently open and inclusive and whether ethical bodies have sufficient resources for establishing different fora for debate. It should be considered whether it would be possible to create a network among the national ethical bodies for example with the view of discussing how they can deal with the ethical issues related to EU-regulation. New methods for involving stakeholders at European level should be developed.

European Group on Ethics (EGE):

7. Objective: **To strengthen the role of the European Group on Ethics (EGE) in the future landscape of European Bio-tech policy**

Suggestions: The possibility for EGE to take into account concerns expressed by other EU bodies than the Commission should be strengthened. The dialogue between EGE and national ethical bodies and the external activities of EGE should be promoted as well as the enhancement of public debate and dialogue.

Securing transparency and co-determination

8. Objective: **To include all relevant stakeholders and strengthen the role of laymen**

Suggestions: It is important to clearly define the role and clarify the aims of involving stakeholders such as consumers, NGO's, laymen etc in bioethical debate and decisions. To ensure a constructive dialogue stakeholders should have access to relevant information about the biotechnology discussed, both the science and the possible impact on society, bioethics. Equal footing is important when laymen are involved. Lay contributions to ethical advice should be improved and should be seen as an easy public access to information on biotechnology.





III. ETHICAL AND SOCIAL CONSIDERATIONS IN APPROVING NEW APPLICATIONS OF BIOTECHNOLOGY

The BioLAW-dimension

9. **Objective: To achieve legitimacy in international trade agreements and the Codex Alimentarius for including ethics and societal benefits with regard to novel applications of gene technology**

Suggestions: The aspiration of the EU should be to promote the recognition of bioethical considerations in product regulation in other international fora i.e. the WTO. Bioethical considerations should be taken into account to the same degree as considerations to the environment, and the protection of exhaustible natural resources are taken into account in the EU and the WTO. When recognising these concerns the risk of increasing trade barriers should also be taken into account.

10. **Objective: To create a transparent and internationally acceptable way of incorporating ethical considerations in the EU-regulation**

Suggestion: The EU should consider how legitimate factors such as ethical and societal concern should be taken in to account when considering the fundamental regulatory principles for biotechnological products.