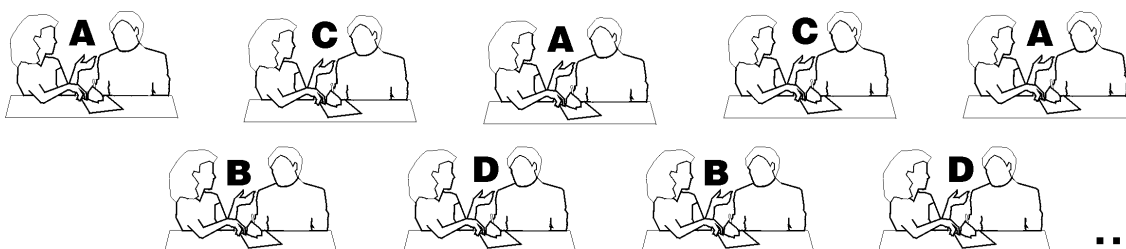


Exercise 1C. Reflecting on Biosafety

(work in pairs)

The aim of this exercise is to identify critical points in biosafety and the information needed at each point to make a good decision and to understand the role law and policy can have both in positive and negative terms.

1. Form a pair with your neighbour. (5 minutes)



Phase 1. Work in pairs (20 minutes)

1. The trainer assigns letters A, B, C, D, E and F to the pairs, repeatedly, until all pairs have a letter.
2. Read the following hypothetical case carefully:

As a result of the unique qualities and possible applications of the *obokun* plant and its derivatives, immense scientific attention has been attracted to it, including attention from the biotechnology sector. The University of Ambria in the Saxony Republic, North Europe, has an ongoing collaborative arrangement with Genetekno, a biotechnology firm also based in Saxony. Researchers from the University's botany and biochemistry faculties have been studying the *obokun* plant for many years. Through the application of a genetic engineering procedure developed by Genetekno, the researchers were able to develop a variety of *obokun*, OPV5, that matures in less than half the natural period of both the wild and cultivated varieties. However, after several field trials in Saxony as well as several other sites in North Europe, it was discovered that they had not retained some of the special properties and compounds of the varieties found in Bugania or the neighbouring countries. Further research revealed that it was the unique composition of the soil in conjunction with the climatic conditions in Bugania that were responsible for the expression of these special properties.

Genetekno has discovered that the only cost-effective and, therefore, most profitable line of action for it to take in order to exploit the potential market for *obokun* and its extracts is to have the University develop seedlings of the genetically modified variety that will be sent to and cultivated in plantations in one of the three countries. To achieve this goal, it has started negotiations with the Bugania Department of Agriculture to cultivate the modified variety in the areas most conducive for it close to the border with Eastania.

Bugania is keen to conclude the agreement with Genetekno because it sees the potential to boost its exports and foreign-exchange earnings and, therefore, its ailing economy.

However, the current administration in Westalia is opposed to genetically modified organisms (GMOs) and is committed to keeping the country, as well as the region, GM free. Being a centre of origin for the *obokun* plant, it is particularly concerned about gene flow and genetic contamination.

Eastania is not particularly opposed to GMOs, and it is open to taking advantage of technologies that could help it develop its agricultural and other sectors, but it is concerned about its lack of capacity to regulate, monitor or deal with any possible adverse effects of GMOs. It is also concerned about possible effects on its local farmers.

Because Bugania is land-locked, it uses Westalia's seaport for its shipments. Further, because of its size and for economic reasons, it does not have its own international airport but, through a special arrangement, uses the airport in Eastania.

The Cartagena Protocol on Biosafety has recently come into force and all the countries, including Saxony, are parties to it. The African Union has also recently developed a Model Law on Biosafety to assist member states in setting their own national laws and institutional arrangements.

3. Respond to the questions assigned to your pair.

Pair A: What are the key legal issues you should consider in a case like this?

Pair B: What are the other major issues for the respective countries, based on their specific situations?

Pair C: What sort of legislative framework and institutional arrangement will best suit the respective countries?

Pair D: What are the key stakeholders (in their order of priority) that should be involved in discussions in the process of establishing

1. the policy framework for biosafety?
2. the legislative framework for biosafety?
3. an administrative framework for biosafety?

Pair E: How best can the cross-border issues be dealt with?

Pair F: What are the areas of concern or issues for consideration by Genetekno?

4. Write your responses on a flipchart or in a transparency provided by the trainer. Use key words and make sure you write clearly using large letters.

Phase 2. Reporting and discussion (45 minutes)

5. The trainer invites rapporteurs from the A, B, C, D, E and F pairs to present the results to the audience.
6. The trainer invites other pairs who had different responses to share and discuss their results.
7. The trainer distributes handout 1C.8 to the participants, analyses practical considerations for this exercise, provides feedback on the context of the presentations and closes the session. (10 minutes).

Exercise 1C — Worksheet

Pair A

Question:

What are some of the key legal issues you should consider in a case like this?

This image shows a blank sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

[illegible]

Exercise 1C — Worksheet

Pair C

Question:

What sort of legislative framework, as well as institutional arrangement, will best suit the respective countries?

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

Exercise 1C — Worksheet

Pair D

Question:

What are the key stakeholders (in their order of priority) that should be involved in discussions in the process of establishing

1. the policy framework for biosafety?
2. the legislative framework for biosafety?
3. an administrative framework for biosafety?

This image shows a blank sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

Exercise 1C — Worksheet

Pair E

Question:

How best can the cross-border issues be dealt with?

This image shows a full page of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page, providing a template for writing or drawing. There are no margins, text, or other markings on the page.

Exercise 1C — Worksheet

Pair F

Question:

What are the areas of concern or issues for consideration by Genetekno?

This image shows a full page of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page, providing a template for writing or drawing. There are no margins, text, or other markings on the page.

Practical Considerations for Exercise 1C

(to be distributed after completion of Exercise 1C)

After doing this exercise, participants are able to identify critical points in biosafety and the information needed at each point to make a good decision and to understand the role law and policy can have both in positive and negative terms.

General Issues

The trainer should look at the general issues raised in Exercise 1C: biosafety; biosecurity (across borders); issues of product liability and redressing; sanitary and phytosanitary issues; and intellectual property rights. Help the participants see how they apply in dealing with issues of biosafety in this hypothetical situation. The exercises are linked and the participants are asked to evaluate the information and answers provided in Exercise 1A for its impact on biosafety in Exercise 1C.

Specific Issues

One of the ultimate goals of Exercise 1C is to facilitate the participants' understanding of biosafety issues.

At the end of the exercise, the participants should demonstrate the following:

- (a) an understanding of the key legal issues involved in biosafety: biosafety clearing mechanisms, the precautionary principle, substantive equivalence, advance informed agreement, contamination and containment of gene flow
- (b) an understanding of the major legal and institutional issues in the respective countries, based on their specific geographic, political, economic and cultural situations:

1. BUGANIA

- | | |
|---------------|--|
| Legal | <ul style="list-style-type: none">• Protection of landrace• Biosafety by bilateral agreements• Intellectual property |
| Institutional | <ul style="list-style-type: none">• Genebank• Biosafety clearing house• Intergovernmental clearing house mechanism |

2. EASTANIA

- | | |
|---------------|---|
| Legal | <ul style="list-style-type: none">• Bilateral agreement on movement of materials• Biosafety• Bilateral agreement of capacity building |
| Institutional | <ul style="list-style-type: none">• Intergovernmental clearing house mechanism• Biosafety clearing house |

3. WESTALIA

- | | |
|---------------|--|
| Legal | <ul style="list-style-type: none">• Gene bank• Biosafety• Bilateral agreement on material movement |
| Institutional | <ul style="list-style-type: none">• Gene bank• Biosafety |

4. SAXONY

- | | |
|---------------|--|
| Legal | <ul style="list-style-type: none">• Material transfer• Access and Benefit Sharing• Biosafety• Legislation |
| Institutional | <ul style="list-style-type: none">• Biosafety clearing house |

(c) the ability to identify and understand the international legal instruments of relevance to biosafety and how they interact with national legislation. The international legal instruments of relevance to biosafety are the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety. The participants are expected to have understood these instruments, with the point of interaction with national legislation being whether the countries are parties or Members to the two instruments

(d) the ability to identify the key stakeholders that should be involved in discussions to establish the policy, legislative and administrative framework for biosafety:

1. scientists (biotechnologists, breeders, agronomists) in national agricultural research centres, universities and private labs/companies
2. extension agencies; both governmental and nongovernmental organizations/community-based organizations
3. farming communities
4. national food quality and safety authorities
5. environmental specialists – environmental-impact assessment
6. national biosafety authority
7. quarantine authority
8. ministry of commerce
9. national seed/plant variety protection authority
10. ministry of health/public health authority
11. ministry in charge of food technology
12. ministry of transport/aviation
13. animal husbandry experts
14. cultural and religious organizations and authorities
15. representatives from neighbouring countries
16. media
17. legal experts
18. customs office
19. national patent authority`

(e) the ability to identify cross-border issues and how they are dealt with:

Cartagena protocol on biosafety

- Transboundary movement of GMO (Biosafety Clearing House, Advance Informed Agreement)
- Sealed containers
- Phytosanitary regulation

Risk assessment/management

- Natural risk of gene flow across the border
- Risk assessment—establishment of minimum buffer zones
- Risk management; physical barriers

(f) the ability to identify the areas of concern for each party involved in biosafety activities.

The areas of concerns are largely based on the legal and institutional issues outlined in (b) above.