Introduction of the draft NBF of Croatia and achievements under the UNEP-GEF project

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GMO - THE NATIONAL BIOSAFETY FRAMEWORK OF CROATIA

UNEP GEF ministarstvo kulture REPUBLIKE HRVATSKE DRŽAVNI ZAVOD ZA ZAŠTITU PRIRODE

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INTRODUCTION

- **Cartagena Protocol**
  - was signed and ratified by Republic of Croatia on 29th August 2002
  - It came in force on 11th September 2004
- **Acquis Communautaire**
  - enforced in Croatia on 1st December 2001
- **UNEP-GEF project of NBF**
  - started on 7th February 2003 in the Ministry of Environmental Protection and Physical Planning (MEPPP), which is National Executing Agency (NEA) for NBF project

HISTORY OF NBF PROJECT IN CROATIA

- **7th February 2003 - December 2003**
  - The MEPPP was the NEA for NBF project
- **2nd April 2004 until now**
  - The State Institute for Nature Protection (SINAP) is the NEA for this Project
  - The Ministry of Culture is funding and supporting the SINAP

MAIN OBJECTIVE AND DURATION OF THE PROJECT

- **The main objective**
  - preparation of a National Biosafety Framework in accordance with the relevant provisions of the Cartagena Protocol on Biosafety
- Originally from 07th February 2003 until 07th August 2004
- It was extended for another 5 months
- The official end of the Project is on **7th January 2005**

NCC

- **The National Project Coordinator (NPC) had been appointed on 15th March 2003**
- **NCC members consist of representatives from:**
  - National Executing Agency for NBF project
  - The Croatian National Institute of Public Health
  - Ministry of Agriculture, Forestry & Water Management
  - Ministry of Economy, Labour and Entrepreneurship
  - Faculty of Science
  - Faculty of Agriculture
  - Faculty of Food Technology and Biotechnology
  - College of Agriculture at Križevci
  - Institute "Ruđer Bošković"
  - Institute of Social Sciences "Ivo Pilar"
  - Pliva d.d. (Pharmaceutical company)
  - Control station for organic-biological production

NCC

- And, from following **NGO's**:
  - Croatian Association of Genetical Engineers
  - Croatian Peasants Association
  - Green Action, Friends of the Earth Croatia
  - Association for Organic Husbandry, Environment Protection and Health Improvement of Croatia

NCC

- The **president of NCC** is Krunoslav Capak MD/MSc from the Croatian National Institute of Public Health
- His **deputy** is Davor Šamota Prof./PhD from the Control station for organic-biological production
- **Ten NCC meetings**
  - held from 20th May 2003 until 19th November 2004

NCC

- Representatives present **on every NCC meeting**:
  - Institute "Ruđer Bošković"
  - Pliva d.d. (Pharmaceutical company)
  - Control station for organic-biological production
  - Croatian Association of Genetical Engineers
  - Association for Organic Husbandry, Environment Protection and Health Improvement of Croatia
- Representatives present on **half of the meetings***:*
  - Ministry of Agriculture, Forestry & Water Management
  - Croatian Peasants Association
  - Green Action, Friends of the Earth Croatia

PROJECT ACHIEVEMENTS

- The NCC is comprised of 16 members
- There is a division of opinion
- Dr. Liina Eek Piirsoo came on 27th April 2004 to Croatia
- Result:
  - UNEP had sent a letter to the Croatian government
- In spite of all this, the Project has achieved the following results...

PROJECT ACHIEVEMENTS

1. Had conducted the National survey of:

- In August 2003 a questionnaire was sent to 280 institutions in Croatia
- A database was created from the results
- We gathered data from 220 institutions with 518 laboratories
- From 518 laboratories:
  - **13% are using biotechnology**
  - **6% had worked with GMO's**
  - **13% had some kind of safety system in place**
  - **5% were implementing principles of Good Laboratory Practice**
  - **2% are in the process of implementing ISO 14000 or ISO 17025**
- The list of 50 national experts was formed

PROJECT ACHIEVEMENTS

- Data on other national or international projects are not kept in one place
- The Ministry for Science, Education and Sports (MSES) is financing projects in Croatia
- To MSES had financed in 2003 in total 1 768 scientific projects = 125 238 000 KN
  - **38%** were biology/biotechnology projects financed with 44% of the total budget (rough estimate)
- From 567 project summaries
  - **12%** could have connections with biotechnology
- In year 2002
  - = 14 % of students had enrolled in faculties that have biotechnology as a subject
  - = 11% had graduated from such faculties (100 persons)
  - **= 40 % of the graduates from such faculties have found related employment**

PROJECT ACHIEVEMENTS

2. A survey on existing mechanisms for harmonisation of risk assessment/risk management, mutual acceptance of data and data validation had been conducted in April 2004 under existing legislation

- Mechanisms are planned but they haven't been operational as yet
- The **new GMO Act** will create changes within it

PROJECT ACHIEVEMENTS

3. A survey on existing national biosafety frameworks in the countries of the sub-region

- Had been conducted in April 2004

PROJECT ACHIEVEMENTS

4. **A survey on the extent and impact of release of LMO's and commercial products had been conducted in April 2004**
   - From 1997 until 1999, there were approved field trials of GMO maize in Croatia by the Scientific Committee appointed by the Ministry for Agriculture and Forestry
   - No permits for the commercial growth of GMO plants have been issued
   - From 1999 until now, not one permit has been issued for field trials or commercial growth of GMO plants
   - From 1999 until now ban on import or production of GMO food products in Croatia
   - Border sanitary inspections have not discovered any GMO food products

PROJECT ACHIEVEMENTS

- From May to October 2003 laws regulating biotechnology and biosafety have been adopted in Croatia
- The two bylaws that have been passed under Nature protection Act are:
  - "The Regulation on the minimum threshold for GMO’s in products below which the products placed on the market shall not have to be labelled as products containing GMO's (Official Gazette No. 34/04)"
  - "The Ordinance on the conditions to be fulfilled by a laboratory for testing, control and monitoring of GMO’s and products containing GMO's (Official Gazette No. 98/04)"

PROJECT ACHIEVEMENTS

- At the beginning of this year, the GMO laboratory began sampling & testing
- In this period two major **GMO incidences** happened:
  - A meat product (sausages) contained GMO Soya
  - "Pioneer" maize seeds that had already been planted

PROJECT ACHIEVEMENTS

5. A review and assessment of existing legislation that may impact on the use of modern biotechnology

- This assessment has been reviewed four times:
  - On 17th July 2003 before the adoption of Nature Protection Act
  - In November 2003
  - In April this year
  - Now by a panel of international experts

PROJECT ACHIEVEMENTS

6. Produced public awareness material and access to information for stakeholders

- We have held 6 workshops - we provided printed materials or CD's
- Glossary
- The booklet entitled "Development of National Biosafety Framework in Republic of Croatia"
- Our web site (www.gmo.hr)

PROJECT ACHIEVEMENTS

7. **The six workshops were held**
8. **Prepare a National Biosafety Framework, including procedures for the safe application of biotechnology in accordance with the Cartagena Protocol on Biosafety (administrative, legislative, risk assessment and public participation systems)**
   - In June, this Project had assembled a team of experts (more than 30) to draft more than 20 by-laws for Nature Protection Act
   - All drafts of bylaws had been delivered to the Ministry in September 2004

PROJECT ACHIEVEMENTS

- **9. Attendance at regional or sub-regional workshops:**
  - **UNEP-GEF Sub-regional Workshop on "Biosafety Framework"**
    (Prague, 23th April - 25th April 2003)
  - **UNEP-GEF - CEECCA Sub-regional Workshops: "Risk Assessment & Management" and Public Awareness & Participation"**
    (Vilnius, 26th May - 2nd July 2003)
  - **UNEP-GEF regional Workshop on "Public Awareness, Information and Participation in National Biosafety System"**
    (Ljubljana, 11th September - 12th September 2003)
  - **UNEP-GEF Biosafety Sub-Regional Workshop on developing a Regulatory Regime and Administrative Systems for National Biosafety Framework**
    (Antalya, 9th - 12th December 2003)
  - **UNEP-GEF - BCH workshop** (Kuala Lumpur, 24th - 26th February 2004)
  - **International workshop in Croatia at Plitvica Lakes on "GMO laws, inspection and labelling of food"** (April 21st - 23rd, 2004)
  - **"World of Food 2004"** (Istarske Toplice, 28th May 2004)
  - **International two-week workshop "Holistic Foundations for Assessment and Regulation of Genetic Engineering and Genetically Modified Organisms"** (Tromsø)
  - **International Biotechnology Information Conference in United States** (October 11th - 15th, 2004)
  - **UNEP-GEF regional workshop for "Implementation of National Biosafety Framework" project** (Prague, 10th - 11th November 2004)

THANK YOU!