

SIXTH FRAMEWORK PROGRAMME
THEMATIC PRIORITY 5
FOOD QUALITY AND SAFETY



ResistVir

Co-ordination of Research on genetic resistance to plant Pathogenic Virus, and their Vectors in European Crops

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Co-ordination Action

Deliverable 16: Exciting recent (Month 14-24) development in legislation, technology practices, regulations, and intellectual property issues seminar

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PU public	PU
PP Restricted to other programme participants (including the Commission Services)	
RE Restricted to a group specified by the consortium (including the Commission services)	
CO Confidential, only for members of the consortium (including the Commission services)	

ResistVir Legislation workshop, Helsinki, 6th July, 2006.

Intellectual Property

Dr Mike Adcock from the Sheffield Institute for Biotechnological, Law and Ethics opened the workshop with a comprehensive presentation about Intellectual Property, the legislation governing this and other issues affecting patents.

▪ Background

In recent years there has been an increase in the global trading importance of biotechnology which has resulted in an extension of patent protection to more and more forms of biological material. In addition there is now increased awareness of Intellectual Property (IP) and therefore greater pressure to protect material by IP.

▪ Legislation

There are 2 sources of European Patent Law;

- 1) European Patent Convention (EPC)
- 2) EU Biotech Directive

The EPC came into force in 1973 and is not a body of the EU although all EU member states are members. The EPC enables an applicant to acquire, via a single application, a patent which is enforceable in as many member states as the applicant wishes. The right once granted has exactly the same effect as if it had been granted by the local granting office, and it is enforceable through the national courts.

The EU Biotech Directive was brought into being because the EU can not revise the EPC but wished to clarify and influence EPC decisions.

▪ What is a patent?

A time limited monopoly granted by the State to the Inventor in return for disclosing the invention to the Public. It can be justified at several levels including being viewed as a reward for the endeavour and the money that was put into the research.

A patent is a negative private property right i.e. it prevents anyone else from exploiting the invention without authorisation e.g. making, using, offering for sale, selling or importing. Patents have a 20 year life. The criteria by which patents are granted under the EPC include;

- 1) Novelty - An invention shall be considered to be new if it does not form part of the state of the art. (Article 54 of the EPC)
- 2) Inventive Step – It must not have been obvious to invent it. (Article 56 of the EPC).
Could someone else in the field have done it ? No.

- 3) Capable of Industrial Application – the invention must be capable of being used (Article 57).

Specific examples of how these criteria may affect the research carried out by members of the Resistvir consortium include determining whether a GM plant can be considered as novel (yes it can) and speculative patenting of EST's which must now cover the sequence and function.

▪ **Excluded material**

European patents cannot be granted for

- 1) inventions the publication or exploitation of which would be contrary to "*ordre public*" or morality (Article 53a of the EPC)
- 2) plant and animal varieties (Article 53b of the EPC)

For Article 53a the leading case in this area is *Plant Genetic Systems v Greenpeace* (T356/93) [1995] European Patent Office Reports 357. This concerned a transgenic plant, which Greenpeace argued would cause harm to the environment. The EPO said that in order for such an argument to succeed there must be evidence of actual, not speculative, harm.

For Article 53b the leading case is *Novartis/Transgenic Plant* [2000] European Patent Office Reports 303 - the Enlarged Board of Appeal overruled the decision of the Technical Board and said that claims which encompass more than one variety are not excluded. Therefore plants are patentable in Europe provided a technical invention can be shown (e.g. plant contains a novel gene) and plant varieties are not claimed specifically.

There are some subtle differences to note between the EPC and the Biotech Directive. The latter provides for farmers' privilege exemption allowing farmers who used farm saved GM seed to reuse them under certain conditions. The Biotech Directive is also much clearer on the scope of protection extending the scope of protection to any plant in which an invention is present.

▪ **How do you get a patent ?**

A patent application must have the following;

- 1) Registration – which includes a list of the inventors and the designated countries
- 2) An abstract – which includes a brief summary, the field of invention, uses and the technical problem that the invention attempts to resolve
- 3) A description of the invention which summarises the prior art
- 4) Claims which cover
 - the scope of the legal protection conferred
 - principle claims

- dependent claims
- the demarcation and definition of the patented invention

There must be a balance between broad and narrow claims. Narrow claims do not cover a wide remit and are therefore less likely to be challenged. Broad claims provide more protection but are more likely to be challenged.

For example; there is a patent covering Pepper Mold Mottle Virus resistance in Capsicums (EP1647182). This patent has 25 claims including the alleles, the method of producing the plant and the sequences used.

Drawings can be included to help explain the claims. When a patent is granted all the information in the application is put together into the bibliographic data.

A patent can be filed at 3 different levels; (i) national; (ii) EPO; (iii) Patent Co-operation Treaty (PCT), each has their own advantages and the choice may well be down to cost.

The date of filing is very important it sets the "priority date". The priority date of a patent application is the date which controls what prior art affects its patentability. This means that only information in the public domain before that date will be considered when assessing novelty. Anything published after that date, but before the patent is awarded will not be considered. Once the application has been filed a preliminary examination and search are carried out. The patent is then published and a substantive examination carried out. Provided all the criteria have been met the patent is granted. However, the patent application can be stopped at various stages and even challenged once the patent has been granted.

The PCT allows a single patent application to be made with a view to getting national patents in various countries as 'international patents' do not exist. In addition application under the PCT has a longer period for considering the patent applications, 30 months in comparison to 12 months taken in the UK. Following filing under the PCT an international search is carried out followed by a preliminary examination. The application then moves from the international phase into the national phase.

▪ **Issues**

Cost is obviously a major issue. Application for a patent under the EPO costs approximately 32 000 Euros and this maybe a conservative estimate. In comparison application for a patent under the PCT costs approximately 47 000 Euros (Source EPO).

Ownership is also a consideration and varies from country to country. In the UK where the invention is made by an employee, in general, the employer will own the patent.

A valid UK or European patent cannot be obtained if the invention has been made known to the public, even by the inventor himself, by written or oral disclosure, by use or in any other way, whether in this country or abroad, at any time before the Patent Application is made. Therefore, if a Patent Application is contemplated it is essential not to disclose the invention to anyone, except under conditions of strict confidence, until the application is actually on file. In U.S. patent law there is a one-year grace period offered where for example, an inventor may discuss his invention at a conference and not destroy his patent application.

In the EU ownership is given to the first person to file while in the US ownership is held by the first person to invent, hence the need for evidence in the form of signed and dated lab books, etc.

- **Patent licences**

Research with patented inventions is permitted but only under a licence. However, to ensure that patented inventions are not being used without a licence, requires policing and enforcing. It may not be worth taking any action until the work with the patented invention reaches a commercial level. Licences can cover a part or the whole of a patent, be issued for different periods of time or countries and be exclusive or non-exclusive.

In summary patents are important but there are many considerations to be taken into account when deciding whether to make a patent application including; cost, the route to take, publishing, freedom to operate and licensing.

Regulations in Practice

Dr Dick Verduin, the Biological Safety Officer from the University of Wageningen and a member of the Executive Council of the European Biosafety Association (EBSA) gave a presentation illustrating how regulations are implemented in practice. In terms of biological safety there are three principle groups of organisms;

- (1) Genetically Modified Organisms (GMO)
- (2) Biological Agents (BA)
- (3) Plant Pathogens or Pests (PP)/Quarantine Organisms (QO).

The containment measures for minimising the risks from each of these groups of organisms are frequently quite similar. The EU directives regulating the use of these 3 groups of organisms are as follows;

GMO Contained Use	90/219/EEC as amended by 98/81/EC
GMO Deliberate Release	2001/18/EC
BA	2000/54/EC
PP/QO	95/44/EEC, 2000/29/EC, 2001/33/EC

In the Netherlands these regulations are implemented by three different Government departments and a combination of Dutch and EU legislation as listed below:

GMO Contained Use, the Dutch GMO-Decree and Environmental Management Act implemented by the Ministry of Housing, Spatial Planning and the Environment (VROM).

BA, the Working Conditions Decree implemented by the Ministry of Economic Affairs and Employment (SZW).

PP/QO the European Directives listed above which are implemented by the Ministry of Agriculture, Nature Management and Fisheries.

Under much of this legislation a notification must be made or a permit applied for which usually requires a risk assessment to be made and appropriate containment measures selected (and may also involve an inspection). However, despite this there is very little cross talk between the three departments. As a point for discussion it was suggested that a single approach could be used for all three groups of organisms.

The specific containment measures are grouped into four BioSafety Levels used for work in a laboratory, plant growth room, greenhouse and animal house in the Netherlands. Photos of the facilities at the University of Wageningen were shown to illustrate the specific containment measures at each BioSafety level. Dr Verduin felt that it would be useful to debate the issue of whether work at BioSafety Levels 1 and 2 should be de-regulated so that risks would be

more proportionately addressed i.e. focus on the medium to high risk work. The Competent Authorities implementing the regulations can be rather rigid in their approach. List based classification methods are often used to determine what BioSafety level should be used for work with a specific organism. However, this categorization makes it more difficult to reduce the BioSafety level even when there is good evidence to show that a lower level should be used. In addition placing a pathogen on a list, for instance Plum pox virus which is on the Select Agents list, often makes it disproportionately more difficult for researchers to carry out work on such pathogens. A proposal was made for a common science-based approach to risk assessment in the EU.

EU Regulatory Framework on GMO's and the WTO Biotech Products dispute

Ilona Cheyne from the Newcastle Law School at the University of Newcastle very kindly agreed at the last minute to replace Dr Andrew Tommey from the DG Environment of the European Commission. She began by giving an overview of the EU Regulatory Framework and then went onto discuss the outcome from the recent WTO Biotech Products dispute.

Currently there are three principle pieces of EU legislation which cover GMOs;

- (2) 2001/18/EC which covers deliberate release
- (3) EC 1829/2003 which covers food and feed
- (4) EC 1830/2003 which covers traceability and labelling

▪ Deliberate release

To carry out a deliberate release under the authorisation of 2001/18/EC, a risk assessment must be made by the national competent authority. If following the risk assessment the competent authority rejects the application, a new application must be made before the deliberate release can progress any further. If the competent authority accepts the application, the Commission is informed and forwards the application to all the other member states for comment. The consent can be issued provided none of the other Member States have an objection. A release can be agreed or rejected by the Council by qualified majority voting and therefore countries can block this process. If the other Member States make objections then an EFSA opinion can be sought. Following delivery of the EFSA opinion the Council of Ministers has three months to adopt a decision.

▪ Safeguard measures

Under 2001/18/EC there is a clause which allows Member States to adopt 'safeguard measures' to restrict or prohibit a GMO at a national level on the basis that it would constitute a risk to human health or the environment. This must be justified by provision of scientific evidence to the EU. Adoption of safeguard measures was one of the issues raised during the WTO dispute.

▪ Labelling and traceability

Products that contain GMOs must be labelled and food or feed derived from GMOs must also be labelled even if GM DNA or proteins are not present. Where the presence of GMOs is technically unavoidable or there is an adventitious presence of GMOs, the tolerance threshold is 0.9% below which the product does not need to be labelled. There is no obligation to label meat, milk or eggs from animals that have been fed GM food or treated with GM medicinal products.

▪ **Background of WTO**

The WTO was established in 1995 as a successor to GATT which was formed in 1947. The WTO Agreement drawn up at the end of 1994 included formal institutional arrangements and a Dispute Settlement Understanding (DSU) which is essentially rules and procedures for settling trade disputes. For instance a dispute between France and Japan was settled in this manner. France had freely allowed the importation of Japanese VCRs but all the machines had to go through 1 customs office in Poitiers which had 1 person working part time. The WTO Agreement covers several areas including: GATT 1994, Sanitary and Phytosanitary Standards (SPS) and Technical Barriers to Trade (TBT). The agreement recognises that governments have the right to take SPS measures necessary for the protection of human, animal or plant life or health. However, the need for adopting these measures must be based on scientific evidence. Governments are encouraged where possible to base measures on International Standards. They may adopt a higher level of protection if there is scientific justification for this via a risk assessment.

▪ **The WTO Biotech Products Dispute**

The USA, Canada and Argentina challenged the EU under the WTO trade rules. A WTO panel was established in May 2003 to look into the challenge and should have come to a conclusion by November 2003 or at the very latest March 2004. In reality the panel issued an interim report in February 2006 with the final report produced in May 2006. The challenge claimed that the safeguard measures introduced by a number of the EU member states were against WTO rules. In addition, it also claimed that a group of EU states had blocked the introduction of GM crops by putting a moratorium in place. The complaints were very carefully and narrowly constructed. The aim of the challenge lodged under the WTO dispute was to force the Commission to enforce the existing legislation. The dispute exposed the fundamental differences between transatlantic countries and the EU. It also introduced environmental issues into trade. The WTO was in a very difficult position because they could not be expected to make a decision about the scientific basis of the arguments.

The WTO panel assessing the challenge focussed on whether the safeguard measures adopted by some of the EU member states could be viewed as covered by the SPS agreement and came to the conclusion that they could. They also came to the conclusion that there had been both a General and National Moratorium. However, the EU said that now the legislation covering labelling and traceability was in place the Moratorium would be lifted. The panel did not decide whether biotech products are generally safe or whether they and their conventional counterparts are like for like. The panel findings were mostly based on procedures. If there are procedures for GM approvals then they should be used in the proper fashion. If EU countries wish to ban GMOs then they should say no and say it clearly. However, every country has a right to introduce the level of protection that it chooses. Following the panels findings, the Commission has put pressure on the individual member states to withdraw safeguard measures. Safeguard measures can only be adopted based on a proper risk assessment with scientific evidence.

It is likely that in the future there will be a dispute based on the labelling and traceability legislation. This imposes a huge cost on importers and may discriminate against small importers thus resulting in an obstacle to trade.

It is important to note that ultimately the political decisions will always override the scientific decisions and frequently there is an uneasy compromise between managing public anxiety,

science and politics. This is a point which could be usefully debated further together with the use of the precautionary principle and the rights of the consumer to choose.

Open Discussion

A brief summary of the presentations highlighting some of the discussion points was given and the floor opened for questions.

Q. The WTO report currently available on the website suggests that the EC has real concerns about GM plants. Is this a real reflection of the EC's views as it provides power and evidence for NGOs?

The report has been leaked and there are suggestions that it is not the authentic text. We should wait for the final report to be published before making assumptions.

Q. Are antibiotic marker genes still allowed in GM plants?

There was a suggestion that there is an EFSA document detailing the 3 classes of antibiotic markers. However, it was generally felt that regulators would not tolerate the presence of antibiotic marker genes as they can be removed by crossing from the final GM plant. In addition removal of the marker genes will also prevent the companies which have patented those genes from profiting.

Q. Currently milk, meat and eggs from animals fed on GM food or feed does not need to be labelled?

Yes, this is currently the case although there was a suggestion that the GM labelling rules may be re-examined.

Q. Products must be labelled if they are derived from a GM plant. Technically what does the definition 'derived from' cover? For instance would this include grafting to a GM plant?

Again there was a general feeling that if a GM plant is involved in the process then it should be labelled. However, more specific scientific advice may be required for such issues.

Q. What is the legal definition of a sufficient amount of information?

With respect to IP there is the burden of proof with sufficient evidence backing up what is trying to be proved. In the case of an independent panel considering deliberate releases of GMOs, when they are asking for more information, it must be a 'reasonable request'.

Q. The issue of the legal definition of GMOs was raised.

The speakers and many of the consortium members agreed that the current definitions are somewhat limited.

Q. When consumers can finally buy GM food, how easy would it be under the current regulations to label food 'GM free'?

This gets into areas of consumer law but for example currently eggs can be labelled as GM free if they have been produced by chickens fed on non-GM or organic corn. There would have to be a complete change of the law in order to only allow labelling of food 'GM free'. There was some suggestion that some food is already labelled GM free even if this is not proven.

Q. Labelling covers DNA and protein but what about RNA?

This is a difficult issue because in some cases RNA can be transferred and or inherited. It is currently not very clear and there are already problems about quantifying DNA, in legal terms. What should be measured and where should this be measured? The JRC have launched an initiative on how to standardise DNA content. The proposal is to use genome haploid equivalents but this will have to be done on a crop basis and what should be done with respect to stacked genes? The question can be asked in another way, is it possible to have products which are GM free? This is technically unavoidable because there could be an accidental introduction.

Q. Are the precautionary principle and science based argument a contradiction?

They can both co-exist in the same legislation and can be viewed as the difference between political and scientific opinion. The EU has been somewhat contradictory about using the precautionary approach but there should be both risk assessment and risk management. Risk management is based on different values for each community. One countries protected species is another countries unprotected species. The WTO allows this and individual countries can decide how to address concerns, for example by safeguard measures but it can also be argued that these act as trade barriers. The question can be asked is the measure proportionate to the risk?

Q. What is an example of Category 4 plant pathogen work?

If Ebola virus was used to infect plants this would be category 4 work because Ebola virus is Category 4. In reality there are no Category 4 plant pathogens although Plum pox virus is listed as a special agent because the USA feared that it could be used for bio-terrorism. This illustrates how extreme regulations can be.

Q. (1) If a gene was isolated from a pepper plant and then transformed back into another pepper plant would this plant still be considered as a GMO? (which doesn't make much sense scientifically)

(2) If a specific cultivar of pepper was used to make the GM pepper plant which was then patented who would the breeding rights belong to?

It is correct that under the current definitions the transformed pepper plant would be considered a GMO and it is likely to stay this way. With respect to the breeding rights there will be a conflict between the person who holds the variety rights and the person who holds the patent. Neither can commercially exploit the plant without the others permission although

the patent holder has rights to use the GM plant for scientific research. Both parties would be expected to come to some agreement and there is a system in place to force agreement and ensure they both have rights.

Q. The scientific community are saddled with the way things are defined, for example GMO's. Are there any ways to challenge this?

A legal challenge would have to be mounted on an EU level and legal interpretation varies on a case by case basis. In the courts if the EU wished to apply the precautionary principle the courts will back this. Therefore in order to make any great changes the policy making process will have to be infiltrated and made more science based. In addition scientists will have to broaden their horizons. Some of the problems are caused by the fact that science is moving faster than the regulations.

Q. What is the precautionary principle exactly?

It is about lowering the point at which you act. A lack of evidence is not sufficiently good reason for not doing something. This was illustrated by the example of considering whether workers in a factory should have been supplied with safety glasses. The probability of workers receiving an eye injury was quite low and safety glasses were not provided. However, there was a one-eyed man who received an eye injury and subsequently went blind. The argument that should have been used for the one-eyed man was that although the probability of receiving an eye injury was low, the consequences of such an injury were much greater and therefore he should have been supplied with goggles. In addition, supplying one pair of safety glasses would have a low overall cost.

The legislation workshop then closed.