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**“PLANT MADE PHARMACEUTICALS IN THE EUROPEAN
UNION – POLICY CHALLENGES FOR THE NEXT WAVE OF
BIOTECHNOLOGY PRODUCTS”**

Armin Spök

Inter-University Research Centre for Technology, Work and Culture, Schloegelgasse 2, A-8010 Graz, Austria, e-mail: spoek@ifz.tugraz.at, phone +43 316 813909-41, fax +43 812661-11.

ABSTRACT

Observing the news media plant-made pharmaceuticals (PMPs) seems to be a particular North American issue. In fact, some 300 field trials and several products approaching the market in the USA are contrasting about 20 field trials in the European Union. Nevertheless, PMPs are about to gain a foothold in the EU. In 2003 the EMEA authorised for the first time a drug derived from transgenic corn. Recently, the European Commission awarded some 12 Mio Euro to an EU-research project on PMPs and the German Parliament commissioned a technology assessment that is focussing on this issue.* The first PMP to reach the market stage might even be launched by an European company. Behind closed doors officials and industry representatives have already started to deal with this issue on this side of the Atlantic.

In the EU genetically modified plants are perceived as least as much a regulatory and a risk issue as they are a business issue. Meanwhile the European Commission has almost completed a legislative framework for marketing of genetically modified organisms as well as derived food and feed. More detailed guidelines for risk assessment and market authorisation

are about to be completed. However, most of EU legislation and guidelines are based on experiences with first generation genetically modified crops.

The paper then investigates how well EU legislation is prepared to deal with specific challenges posed by PMPs and plant-made industrials (PMIs) and focuses on regulatory issues and policy activities in these contexts. Frequent reference will be made to the US and Canadian debate and legislative approaches, which will serve as a foil. Given the differences between the US and the EU in the regulatory regime and in public perception it will also be discussed whether in the EU context this new technology would actually be able to deliver what proponents are presently promising.

(*) The author of this abstract contributed to this project.