Europaudvalget EUU alm. del - Bilag 355 Offentligt

GM MAIZE 59122: POSITIVE VOTE IN COMMITTEE FOR EU IMPORT, FOOD AND FEED USE

The EU Standing Committee under Regulation (EC) No 1829/2003 is scheduled to vote shortly on the approval decision of GM maize 59122 for <u>'food and feed uses, and import and processing'</u>. This dossier (**Ref: EFSA-GMO-NL-2005-12**), submitted by Pioneer Hi-Bred International, Inc., a subsidiary of DuPont as represented by Pioneer Overseas Corporation, and by Mycogen Seeds, a subsidiary of Dow AgroSciences, has received a positive safety opinion from the European Food Safety Authority (EFSA). 59122 maize, known commercially as Herculex® RW, provides in-plant protection against larval stages of corn rootworm pests. 59122 maize is as safe as conventional maize and offers benefits to producers, the environment and to consumers. Given the fact that 59122 maize is approved in ten other countries and being grown extensively in the United States in 2007, it will become increasingly difficult for the EU feed industry to source certified maize gluten feed and other derived products without traces of 59122 maize at reasonable costs. In line with the EFSA's comprehensive safety assessment and the positive opinion on 59122 maize, the European Commission is urging Member States to vote positively on this dossier in order to avoid further trade disruption. In summary, Member States are urged to approve 59122 maize at this meeting for the following reasons:

1. 59122 maize meets all EU safety evaluations:

- Positive opinion from GMO Scientific Panel of the European Food Safety Authority (EFSA).
- Safe history of other approved Bt maize events.
- 59122 maize contains no antibiotic resistance marker gene.
- 59122 maize meets the latest EU regulatory requirements and approval should be given without further delay.
- 2. Approval will avoid further negative trade implications for the European livestock sector:
 - 59122 maize is already approved in ten countries around the world.
 - Imports of maize products contribute to the competitiveness of large sectors of the EU livestock industry which rely on maize gluten feed as a high quality, inexpensive feed input.
 - Approval will further avoid disruption of trade with countries already producing 59122 maize.
- 3. Member States are responsible for making the approval process that they put in place work:
 - EU Member States have agreed to the regulatory framework for the approval of new biotech products, including the timeline established for processing these applications.
 - 59122 maize dossier for EU import, food and feed use was submitted in January 2005 well ahead of the times prescribed in the regulations for approval.
 - EU Member States should vote positively for new biotech dossiers once they are assessed as safe by the EFSA, the EU's independent scientific body.
 - Once a positive safety opinion is given, any delay to the approval of products increases the risks of further trade disruption –reason why the EU Commission urges Member States to vote positively.
- 4. Approval demonstrates Member States' commitment to sustainable agriculture:
 - 59122 maize provides environmental benefits to agriculture by increasing yield on the same amount of land with fewer inputs such as chemical pesticides.
 - Approval of 59122 maize will signal Member States' commitment to sustainable agriculture.

59122 MAIZE PRODUCTS WILL BE LABELLED IN FULL COMPLIANCE WITH PREVAILING EU RULES, ENSURING CONSUMERS' ACCESS TO TRANSPARENT INFORMATION AND CHOICE

The Applicants



Since 1926 when Pioneer started breeding and commercializing hybrid maize, farmers around the world have continued to endorse the company's commitment to develop innovative plant genetics that meet the changing

needs of agricultural producers. In adding modern biotechnology to its traditional capabilities, Pioneer and its parent company, DuPont, are guided by principles based on long experience in using science and innovation in a safe, responsible manner. For more information regarding our commitment to these principles, please visit:

http://www.dupont.com/biotech/difference/principles.html

Dow AgroSciences AgroSciences, a global leader in providing pest management and agricultural solutions, is committed to offering farmers a balanced array of crop protection solutions - conventional and biotech. Dow AgroSciences is committed to the principles of Responsible Care* and applies strict environmental, health and safety standards to its research and development process. For more information about Dow AgroSciences and its involvement in plant genetics and biotechnology, please visit: http://www.dowagro.com/pgb/

Dow

FURTHER DETAILS:

1. 59122 maize meets all EU safety evaluations:

After careful evaluation of all the extensive safety studies of 59122 maize, the opinion of the GMO Scientific Panel of the European Food Safety Authority (EFSA) concluded in March 2007, that:

" GMO Panel concludes that maize 59122 is unlikely to have any adverse effects on human and animal health or on the environment in the context of its intended uses."

http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/gmo_maize59122.html

Furthermore, the type of protein (*Bacillus thuringiensis* – commonly referred to as '*Bt*') which protects 59122 maize against various insect pests has in fact been widely used by organic farmers for many years. Similarly, 59122 maize presents no concerns related to hybridisation with wild populations in Europe. Notably 59122 maize contains no antibiotic resistance marker gene. As a consequence, and because it meets the latest EU regulatory requirements, 59122 maize should have a fair and equitable opportunity to compete with other products that have already been approved in the EU. 59122 maize should thus be approved without further delay.

2. Approval will avoid negative trade implications for the European livestock sector:

In 2003, the EU-25's net imports of maize were 3.45 million tonnes of grain and 3.53 million tonnes of gluten feed (Eurostat). More than two-thirds of the EU's maize gluten feed demand is met through imports, primarily from the United States, where it is processed from mixtures of non-GM and GM maize. The importance of maize imports for the European livestock sector rests on the fact that maize gluten feed is a relatively inexpensive, protein-rich animal feed input that would cost more to be substituted by either non-GM maize or other protein alternatives including wheat gluten feed. As more farmers are growing 59122 maize, it is increasingly becoming an essential ingredient in animal feed around the world. EU approval without further delay will signify Europe's desire to continue this important trade flow.

3. The EU must process biotech approval applications in line with EU regulations:

Compared to other biotech regulatory systems around the world, the EU approval system for biotech products presently takes far longer to reach a decision and is often unpredictable. On average, in the ten countries where 59122 maize is already approved, the approval process took on average 18 months from application to approval. These countries have regulatory systems that are predictable, with independent scientific assessment providing the basis for timely approvals. By contrast and even though the 59122 maize dossier was submitted in January 2005 well ahead of the approval times prescribed in the EU regulations, the unpredictable nature of the EU approval system can result in trade flow problems between Europe and the rest of the grain commodity trading nations. However in this case, the problem can be resolved by a qualified majority of EU Member States voting according to the positive scientific opinion given by the EU's independent scientific body, the EFSA, to approve 59122 maize swiftly and still within a reasonable timeframe. Thus reducing the potential for further trade disruption and sending a positive signal to the rest of the world that the EU approval system is functioning according to the rules established by the EU Member States. This is why the European Commission is urging Member States to vote positively on this dossier.

4. Sustainable agriculture and the Environment:

Consumers are paying more attention to how their food is produced, especially regarding the impact on the environment. GM crops and 59122 maize in particular, represent an important tool that contributes to the production of food and fibre while increasing the sustainability of farming. Examples of sustainable advantages of 59122 maize include less use of pesticides and greater production using the same area of land. Furthermore, 59122 maize affects only those target insect pests that attack the maize plant, while broad application sprays may harm both target and non-target species. Approval of 59122 maize will demonstrate an informed understanding of the role that biotechnology can play in meeting consumers' concerns regarding sustainability and the environment. Furthermore, the timely approval of the 59122 maize 'food and feed and import and processing' dossier will be a positive step towards allowing similar benefits for the European environment when the pending 59122 maize 'cultivation' dossier is presented for approval by the EU Member States.

Further details of the safety of 59122 maize is available on the DuPont website: <u>http://www2.dupont.com/Biotechnology/en_US/products/herculex_rw/herculex_rw.html</u>

If you would like additional copies, please contact Mike.Hall@Pioneer.com

Herculex Insect Protection technology by Dow AgroSciences and Pioneer Hi-Bred. ®Herculex is a registered trademark of Dow AgroSciences LLC.