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9 February 2004

SENT BY: REGISTERED POST

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Objection to Public Notice by Monsanto SA (Pty) Ltd, Published in *BUSINESS DAY*, Monday, 19th January 2004: Application for commodity clearance permit for genetically modified wheat

We, the undersigned organisations, groups and individuals, hereby lodge our objections to the above application.

We trust that you will give us timeous notice of any decision made in respect of the application. In the event that Monsanto's application is granted, we expect to receive reasons therefore.

We hereby also inform you that it is our every intention to vigorously review/appeal any decision granted in favour of Monsanto's application.

We look forward to hearing from you.

Mariam Mayet

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We, the undersigned organisations, groups and individuals, hereby lodge our objections to the above application.

We ask that the decision-making authority, the Executive Council established in terms of the Genetically Modified Organisms Act (No. 15 of 1997) ("GMO Act") either on its own, or in consultation with the Advisory Committee reject Monsanto's application.

We are of the firm belief that ample grounds exist for Monsanto's application to be rejected out of hand, alternatively, that Monsanto's application is rejected on the basis of the precautionary principle, which is well established in the body of environmental law and policy in South Africa.

Our objections are principally based on the following, which is fully canvassed in this document:

1. **Monsanto has not been able to discharge its onus of proving that its Roundup Ready genetically modified (GM) wheat is safe for human and animal consumption, biodiversity and the environment and is therefore not in a position to submit adequate scientific data for consideration under the GMO Act for any or any reliable food, feed and safety assessment to be made.**

2. **Monsanto's Roundup Ready GM wheat is unsafe for human and animal consumption and poses unacceptable risks to human and animal health, biodiversity and the environment.**

3. **Monsanto's application and the provisions of the GMO Act/Regulations are inconsistent with the intention, spirit, objectives, principles and provisions of the Biosafety Protocol.**

4. **Monsanto's application is calculated to exploit the biosafety regulatory deficiencies inherent in the GMO Act, in order avoid complying with the Biosafety Protocol. Monsanto's underlying motive for this application is to convince regulatory authorities and farmers in North America that markets for its Roundup Ready GM wheat exist. The application is also a pre-emptive bid to secure access to the lucrative African wheat market when GM wheat becomes available for commercial production in the future.**

5. **The GMO Act does not provide any or any adequate biosafety measures to protect the environment from negative ecological impacts during the transportation and milling of genetically modified organisms (GMOs) imported for direct use as food, feed and processing.**

DETAILED OBJECTIONS:

Our detailed objections are dealt with under the following headings:

1. Notice by Monsanto

On the 19th January 2004, Monsanto SA (Pty) Ltd ("Monsanto") published a Notice in the BUSINESS DAY, announcing that it had applied to the Directorate: Genetic Resources National Department of Agriculture (DGR) for *a "Commodity Clearance Permit number for transgenically modified wheat."*

The Notice makes 2 further public assertions:

1. *"**A commodity Clearance Permit allows for the importation** only of transgenic grains as Food for Human Consumption and the manufacture of Animal Feeds, throughout South Africa. The grain when imported will not be planted, grown or introduced into the environment but milled directly as it enters the country. (own emphasis).*

2. *The purpose of this application is for a **Food, Feed and Human safety assessment in terms of the GMO Act, (No 15 of 1997) to be conducted and a commodity clearance permit obtained.** This will eventually allow importers of wheat to import wheat grain that may contain kernels of Roundup Ready wheat, when such varieties of wheat have been commercially released into the environment of the major wheat exporting countries like the USA and Canada."* (own emphasis).

Monsanto's Regional Director, Mr Wally Green has in the media, particularly on 702 Radio on the 22nd January 2004, contradicting its public notice, denied that it was seeking an import permit, and stated that is seeking only a commodity permit *number*. He however, conceded that Monsanto is seeking a safety assessment from the South African government.

It must be noted that nowhere in either the GMO Act or its Regulations[1], **does the concept of a Commodity Clearance number exist.**

Nevertheless, Monsanto's Notice clearly states upfront that:

(a) It is seeking a commodity clearance permit for genetically modified wheat, to wit, its Roundup Ready GM wheat;
(b) That a Commodity Clearance permit allows for the importation of its Roundup Ready GM wheat to be used as Food for human consumption and the manufacture of Animal Feeds;
(c) Its explicit purpose for "***this***" application is for a Food, Feed and Human Safety assessment in terms of the GMO Act.

2. Implications of a Commodity Clearance Permit

Commodity Clearance Permit is not defined in terms either of the GMO Act or its accompanying Regulations. In fact, the concept of a Commodity Clearance Permit does not exist in the GMO Act itself, but was introduced only 2 years later through the back door by the Regulations in that it appears only on an annex to the Regulations, namely, on Table 3 under the title "***GENETICALLY MODIFIED ORGANISMS THAT HAVE BEEN CLEARED FOR COMMERCIAL RELEASE AND/OR FOR FOOD AND ANIMAL FEED ONLY***"

No special measures exist in the Regulations to deal with the approval process involved in obtaining a commodity clearance permit. Certainly, "permit" on its own is defined as ‘written approval" in terms of section 1 the GMO Act, but there are no explicit regulatory mechanisms or processes in either the GMO Act or its Regulations to deal with an application for a commodity clearance permit, as is now being sought by Monsanto.

Notwithstanding the lack of such measures, Commodity Clearance permits have been granted in the past in terms of the GMO Act. The decision-making authority, namely the Executive Council will therefore use the GMO Act anyway, to clear Monsanto's Roundup Ready GM wheat for food and animal feed**.** In this event, and herein lies our major concern, no further permits will need to be obtained in the event that the Roundup Ready GM wheat is cleared for food and animal feed, as Monsanto is now seeking. In other words, once a GMO is so cleared, and here we can only assume that such clearing means the granting of a Commodity Clearance Permit, then in that event, in terms of section 2(2) of the Regulations, no further permit will be required for the **import to or export** from **South Africa, the development, production, use, release or distribution throughout South Africa of the GMO in question.**

The wording of section 2(2) is peremptory, and read together with section 2(1) provides as follows " …*a permit* ..***shall not be required*** *[for the import, export, development, production, use, release or distribution of any GMO in the Republic of*

South Africa]…for those organisms specified in Table 3 of the Annexure." (own emphasis).

Thus, once Monsanto obtains a Commodity Clearance permit, the GMO Act expressly exempts future importers of the Roundup Ready GM wheat from obtaining an import permit in terms of the GMO Act. This situation will prevail, notwithstanding that at this point in time, the Roundup Ready GM wheat does not exist and irrespective of the fact that no approval exists for the commercial use of the GM wheat in the countries where safety experiments and evaluations are still underway, and indeed, where such approval is several years away from being granted.

This situation is not consistent with intention, spirit, objectives, principles and provisions of the Biosafety Protocol for the reasons set out in section 4 below.

3. Failure to discharge onus of proving safety

The central question that must be answered is, on what scientifically produced data will a food, feed and human safety assessment be made?

3.1 Failure To Obtain Regulatory Approval In Countries Where Safety Assessments Underway

The GM wheat in question has been genetically engineered to tolerate the herbicide, glysophate (known as Roundup Ready) wheat. GM wheat is not grown commercially in any part of the world. Open field trails with GM wheat have taken place in 6 countries-the USA, Australia, Spain, Belgium, the UK and Canada. Laboratory and greenhouse based experiments with GM are also taking place in many other countries, including China, Denmark, Egypt, Kenya, Germany and Switzerland.

To the best of our knowledge, no experimental testing has taken place in South Africa concerning GM wheat generally, or Monsanto's Roundup Ready GM wheat in particular. Even if such experiments are or have taken place in South Africa without our knowledge, such experiments are not relevant inasmuch as Monsanto is seeking a clearance permit for the import of its Roundup Ready GM wheat in anticipation that the said GM wheat would become available for import from the US, Canada and other wheat exporting countries.

It therefore becomes extremely relevant for the Executive Council and the Advisory Committee to be fully appraised of the situation in Canada and the US, in regard to Monsanto's Roundup Ready GM wheat to fully appreciate and understand the grounds upon which these objections are based and more particularly, our assertion that Monsanto has not discharged its onus of proving safety, taking into account that Monsanto Corporation and Monsanto Canada have applied for regulatory approval for its Roundup Ready wheat in both the USA and Canada, respectively.

(i) Situation in Canada

Monsanto Canada filed application on the 23 December 2002 for regulatory approval for Roundup Ready GM wheat to the Canadian Food Inspection Agency (CFIA) for general cultivation and for livestock feed. An application was also submitted to Health Canada on the 31 July 2002 for human safety approval.

However, to date, neither the CFIA nor Health Canada have granted such approval, despite more than 3 years of research in 53 research field trials. Monsanto Canada also needs additional authority from the Pest Management Agency before Roundup Ready wheat can be commercially introduced in Canada.

Monsanto Canada's failure to obtain such approval is partly due to the groundswell of resistance from farmers and farmer organisations in Canada. Two years ago, the organic farmers of Saskatchewan filed a class action lawsuit to stop Roundup Ready wheat.[2] On May 27, 2003, the Canadian Wheat Board (CWB), a farmer-controlled grain marketing agency called on Monsanto Canada to withdraw its environmental safety assessment. In a letter to Monsanto Canada's President, Peter Turner, the CWB stated that approval would lead to "economic harm, which could include lost access to premium markets, penalties caused by rejected shipments, and increased farm management and grain handling costs".[3]

Recently, Agriculture Canada announced that it was abandoning its long running project involving GM wheat it had been developing in partnership with Monsanto. Jim Bole from the government department of Agriculture Canada said that this decision reflected the concerns of Canada's wheat customers.

On the 3rd January, Monsanto Canada announced that it would not in fact ask an advisory body to consider any of its Roundup Ready varieties for registration in 2004. This means that it will not be introduced this year even if the crop passes other regulatory hurdles.[4]

(ii) Situation in the USA

Currently, the US Food and Drug Administration (FDA) is conducting a voluntary safety review of Monsanto Corporation's Roundup Ready wheat for human and animal consumption. Monsanto Corporation is also awaiting approval from the U.S Department of Agriculture (USDA) and the Environmental Protection Agency (EPA.) The FDA, USDA and EPA share regulatory oversight for GM crops.

It must be noted that the FDA does not oversee an independent, mandatory safety assessment process to determine the impact of GMOs on human health. As noted by a report released by the Pew Initiative on Food and Biotechnology "the FDA currently has no affirmative post-market inspection or compliance program for GM crops or foods." In addition to this, the FDA does not "conduct any product sampling or inspection related to biotech foods."[5] The FDA merely oversees a voluntary system under which corporations submit their own safety test procedures for their products, often with only partial data. The FDA thus only considers the company's own assessment of its products and the data on which this assessment is based often remains secret.

Hugh Grant, Monsanto Corporation's Chairman and chief executive officer has said that it would likely take the US government two to three years to approve the wheat. Monsanto Corporations' officials have insisted that even if approval were granted, it would not market GM wheat until growers and consumers were comfortable with it.[6] However, as can be seen from the statements by North American farmers, farmer organisations and consumers set out in **Annex I** hereto, these groups are opposed to GM wheat.

It is our contention that Monsanto has not discharged its onus of proving that its Roundup Ready GM wheat is safe for human and animal consumption and therefore is not in a position to submit adequate scientific data for consideration under the GMO Act for any or any reliable safety assessment to be made**.** The Executive Council is therefore not in a position to make an adequate or reliable biosafety assessment of Monsanto' GM wheat

We submit that scientific evidence as to the safety of Roundup Ready GM wheat for human and animal consumption, biodiversity and the environment is not currently available. Any scientific data that Monsanto submits in support of its application must therefore be approached with the utmost caution and be rejected on the basis of the precautionary principle.

In any event, although there is no onus upon us to do so, we submit the following in support of our submission that Monsanto's application should be rejected as unsafe for human and animal consumption and for posing unacceptable risks to human and animal health, biodiversity and the environment.

(a) Human health safety concerns

Wheat forms an important part of the diet of millions in South Africa who rely on it as a source of carbohydrates. The whole grain is rarely consumed, but it is subject to processing to produce flour or semolina, by milling or grinding. Monsanto is seeking a commodity clearance permit with the express intention that the GM wheat be milled. During milling, high temperatures are not used to break down DNA. Whilst DNA may be degraded to some extent during cooking, intact DNA may be present in food and thus gene transfer to microorganisms in the intestines is possible. A very recent study conducted at the university of Newcastle in the United Kingdom found that DNA could survive to the small intestine and that low frequency gene transfer to the gut microflora of gene fragments may have occurred. The scientists had set out to study the survival of the transgene *epsp* from GM soya in the small intestine of human ileostomists, people with a colostomy bag.[7] In many of the GM wheat varieties being tested, genes giving resistance to the antibiotics neomycin and kanamycin are present. If these genes were transferred to disease causing organisms, they may compromise antibiotic treatment.

(b) Gene instability

It is also extremely important that the Executive Council and the Advisory Committee note that all applications of GM wheat have encountered massive technical problems with regard to the genetic transformation of wheat. The genome of wheat is 10-20 times larger than that of cotton or rice making it much more difficult to reliably genetically modify[8], and transgene silencing, instability and rearrangements are common problems with GM wheat.[9] [10] [11]Transgene silencing, where the activity of the gene is reduced or abolished is a particular problem with multiple copes of genes. Silencing in wheat may be progressive over several generations and arises both from methylation of the genes so they are not transcribed and at the post-transcriptional stage. Not all transgenes transferred in one event are affected in the same way (one may be silenced while another may be expressed) and environmental changes may trigger silencing. This means that there can be many unintended and unpredictable effects, both for the environment, and human and animal health.

The type of promoter used also influences transgene silencing. The cauliflower mosaic virus (CaMV) 35S promoter is particularly vulnerable to transgene silencing effects in wheat.[12] The recombination ‘hotspot'-a site prone to break and rejoin-associated with the CaMV promoter also suggests that transgene constructs with the promoter may be structurally unstable and prone to horizontal gene transfer and recombination, with all the attendant risks.[13]

These technical problems raise practical questions both for the success of GM wheat in the short term, but also about whether gene stability can be guaranteed under the varying environmental conditions, which may be experienced. It will not be possible to mimic all possible situations in field trials and therefore elements of doubt and performance will remain.

(c) Environmental Impacts

We are deeply concerned about the negative environmental impacts that may arise from the spillage of whole GM wheat grains during transportation and the milling process itself. Wheat kernels may remain in the soil, germinate and emerge as wheat ‘volunteers'. If wheat volunteers are herbicide tolerant, they could become much more difficult for farmers to control. Wheat volunteers are a major problem because they can carry viral and fungal diseases over from one season to the next, which may then spread to neighbouring fields. The persistence of GM volunteers could also add to gene flow, as the GM wheat could cross-pollinate with wheat grown in the field in later seasons. Movement of the introduced, foreign gene(s) from GM wheat could take place through crossing with related wild species, with other non-GM wheat plants in the vicinity or via non-sexual transfer to unrelated species such as soil microorganisms.

The potential for gene glow is important for two reasons:

- wild related plants may acquire foreign genes leading to the evolution of more problematic weed species or damage to ecosystems;
- neighbouring organic or conventional non-GM farmers may be unable to sell their crop if it becomes contaminated.

We therefore note with alarm that the transportation of GMOs as well as the mills to be used in the processing of GMOs is captured by the extraordinarily wide definition of contained use in section 1 the GMO Act. Contained use is defined to mean *"any activity in which organisms are genetically modified or in which such genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers or a combination of physical barriers together with chemical or biological barriers or both are used to limit contact thereof, with the environment."*

We strenuously dispute this definition, because the transportation of GMOs and indeed, the milling thereof, is in fact a release, requiring appropriate and adequate biosafety measures (which do not in any event exist in terms of the GMO Act) that are

designed to prevent ecological harm. This is particularly pertinent given that the GMO Act exercises regulatory functions in respect only of those facilities where actual genetic modifications are conducted. Only academic and research institutions and bodies involved in genetic modifications under contained use, may be required to be registered.[14]

Our objections to the deeply flawed and biased provisions of the GMO Act cannot be overemphasised enough. We submit that the GMO Act does not provide any or any adequate level of safety to ensure the protection of biodiversity and the environment from the negative impacts of Monsanto's Roundup Ready GM wheat.

In the light of what has been discussed, we are of the firm belief that ample grounds exist for Monsanto's application to be rejected out of hand, alternatively, that its application be rejected on the basis of the precautionary principle, well established in the body of environmental law and policy in South Africa. We further submit that the regulatory deficiencies in the GMO Act do not provide adequate biosafety measures to ensure protection of biodiversity and the environment. The Executive Council is obliged to uphold our rights to a safe and healthy environment, as enshrined in the Constitution. Granting Monsanto's application will undermine such rights.

4. Monsanto's Application and GMO Act/Regulations are inconsistent with the Cartagena Protocol on Biosafety

South Africa is a Party to the Cartagena Protocol on Biosafety (Biosafety Protocol), it having ratified the Biosafety Protocol on the 14 August 2003. The Biosafety Protocol became binding on South Africa on the 12 November 2003. In terms of Section 231 of the Constitution of the Republic of South Africa, 1996, an international agreement such as the Biosafety Protocol is binding on South Africa.

As a Party to the Biosafety Protocol, South Africa is in terms of Article 2(1) of the Protocol obliged to take necessary and appropriate legal, administrative and other measures, to implement its obligations under the Protocol. As such it must ensure that activities carried out within areas under its jurisdiction or control are in accordance with the pertinent obligations, and in doing so, may use legal, institutional and other means through which to achieve implementation.

The food and feed safety assessment and approval sought by Monsanto is in respect of ***non-existent GM wheat***, whereas the Biosafety Protocol applies to real situations of cross border trade in genetically modified organisms (GMOs) and not to speculative trade in respect of non existent GMOs. An early decision now in favour of the import of Monsanto's GM wheat, relieves South Africa of the obligation later, to abide by the regulatory requirements of the Biosafety Protocol, including its critically important Precautionary Principle. Such a pre-emptive move by Monsanto is clearly calculated to undermine the spirit, intention, principles and objectives of the Biosafety Protocol.

It is our contention that Monsanto's application is an attempt to avoid regulation under the Biosafety Protocol, precisely because section 2(2) of the Regulations creates a regulatory loophole. Assuming Monsanto's application were to succeed, its Roundup Ready GM wheat will then be cleared for food and feed, and therefore, in terms of section 2(2) of the Regulations, when the GE wheat becomes available for import from either the US or Canada, no further import permits will in that event be required. In other words, no further approval for the import will be needed in terms of the GMO Act. This situation is inconsistent with the Biosafety Protocol.

The clear intention of the Biosafety Protocol in respect to LMOs traded for direct use for food, feed and processing (LMO FFPs) is that prior to such trade, regulatory approval must already exist for use on the domestic market of the Party of export. This is borne out crisply by the provisions of Article 11 of the Biosafety Protocol, which is wholly based on the assumption that domestic approval for the LMO FFP in question already exists. The entire Article 11 is in fact crafted around this very notion.

Article 11(1) of the Protocol goes further than requiring mere authorisation. It requires that a Party of export inform other Parties to the Protocol of its decision (approval) through the Biosafety Clearing House by way of furnishing to the Biosafety Clearing House, at a minimum, the information specified in Annex II of the Protocol titled "*Information Required Concerning Living Modified Organisms Intended for Direct Use as Food or Feed, or For Processing."* [15]

These requirements put the other Parties to the Biosafety Protocol "on notice" that the LMO in question may be exported for food, feed and processing use; and to provide relevant information on that LMO in order for such other Parties to use in making a decision whether or not to allow the import of that LMO for food, feed or for processing. In other words, this information sharing that follows from domestic approval, serves as a "trigger" to potential importers that the cross-border trade of the LMO in question may commence, subject to the provisions of the Biosafety Protocol.

This intention of the Biosafety Protocol is further strengthened by the provisions of Article 24(2), which addresses instances where domestic approval is granted by a country of export in respect of an LMO, but where such country is not a Party to the Biosafety Protocol. In terms of section 24(2) of the Biosafety Protocol, South Africa is **obliged** to encourage non-Parties such as the United States and Canada to adhere to the Protocol and to *"contribute appropriate information to the Biosafety Clearing House on living modified organisms released in, or moved into or out of, areas within their national jurisdiction*."

It stands to reason therefore that the Biosafety Protocol clearly intends that prior approval of an LMO must already exist for commercial growing; use on the domestic market and export in the Party/country of export, as a first step in the chain of

international biosafety regulatory events that pertain to the cross border trade in FFP LMOs. It is also the intention of the Biosafety Protocol that the second step in that chain is the notification by the Party/country of export through the Biosafety Clearing House. The third significant step in this chain contemplated by the Biosafety Protocol is the consideration of the application and decision-making based on the precautionary principle as enshrined in Article 11(8) of the Biosafety Protocol by the Party of import, which expressly reaffirms the right of importing Parties to ban or severely restrict imports of LMOs in the face of scientific uncertainty.

Monsanto's application and the provisions of the GMO Act/Regulations are therefore in conflict with the spirit, intention, objectives, provisions and principles of the Biosafety Protocol. As a Party to the Biosafety Protocol, South Africa is obliged to reject Monsanto's application.

5. Motivation behind Monsanto's application: pre-emptive bid to pave the way for control over lucrative wheat market in Africa

Monsanto Corporation needs the lucrative African wheat market. Its loss widened to $97 million it its fiscal first quarter in 2003, and this excludes its $69 million goodwill write off related to its global wheat business.[16] The major wheat importers in Africa include Egypt, Morocco, Algeria and Sub-Saharan Africa. North Africa imports approximately 18 million tons of wheat per year, and Sub-Saharan Africa approximately 10 million tons.

Even the US government has cited Africa as a major market for its wheat, especially since competition from the European Union (EU) and Russia is not as fierce owing to dwindling wheat exports from these countries. The US expects its exports to climb to 30 million tons during 2004, an 8-year high, and "sales to Africa will be a major reason."[17]

South Africa has regrettably become a net wheat importer, having imported 1.2 million tons of wheat during 2003, owing to the worst crop in a decade.[18] This situation, however, makes South Africa particularly vulnerable to pressure by Monsanto to grant its application.

The provision of wheat as food aid is also an important factor for the push for the African wheat market. For instance, Ethiopia, the centre of diversity of wheat, imported 600, 000 of wheat last year as food aid from the US and EU.[19]

A commodity clearance permit will greatly assist Monsanto to convince key African importers who have already voiced concern over GM wheat that it is in fact safe. Consider for example the following statements:

"*On January 5, Algeria, which imports large amounts of durum wheat from the United States, announced that it would not import any genetically modified wheat. Egypt and Saudi Arabia are taking a similar tack with respect to wheat"* [20]

"If you have just one grain in a thousand which is genetically modified, the consumer is going to refuse it."[21]

Thus, the granting of the application sought by Monsanto will greatly assist it to capture the African market by importing such GE wheat from the US (once approval is granted in that country). South Africa is hence, the entry point for the export of GE wheat into the rest of Africa.

In considering Monsanto's application, the Executive Council and the Advisory Committee must be fully cognisant of the huge profits that Monsanto stands to make, if South Africa continues to be used by Monsanto as its springboard into the African commodities and seed market.

In the light of the objections submitted herein, we demand that the Executive Council and the Advisory Committee reject Monsanto's application. We demand timeous notice of any decision made. In the event of a decision being made in favour of Monsanto, we demand reasons therefore. We hereby place on record that it is our every intention to vigorously appeal/review any decision in favour of Monsanto's application.

ENDORSEMENTS

SAFE FOOD COALITION: CONTACT PERSON- ANDREW TAYNTON: **taynton@cdrive.co.za**

EKOGIA FOUNDATION: CONTACT PERSON-GLENN ASHTON **ekogaia@iafrica.com**

STEERING COMMITTEE, SOUTH AFRICAN FREEZE ALLIANCE ON GENETIC ENGINEERING (SAFeAGE), a is a broadly representative network of organisations and individuals calling for a moratorium on the growing, sale, import and export of GM crops and food until such time as the necessity, desirability and safety is properly shown for the use of these novel organisms. CONTACT DETAILS: safeage@mweb.co.za

EARTHLIFE AFRICA ETHEKWINI CONTACT PERSON: BRYAN ASHE bryan@earthlife.org.za

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WRAY WHITE: CONTACT DETAILS: wray@natpro.net

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ENDNOTES

[1] These Regulations are the only ones in existence at the moment. They came into effect on the 1 December 1999.

[2] For further information, see http:// www.saskoragnic.com

[3] CWB asks Monsanto to put the brakes on Roundup Ready wheat, 2003 CWB news release http://www.cwb.ca/en/news/release/2003/052703.jsp

[4] Monsanto delays registry of Roundup Ready wheat, National Post, Canada January 3 2004 http://www.gmwatch.org/archive.asp

[5] *Post-Market Oversight of Biotech Foods-is the system prepared?* A report commissioned by the Pew Initiative on Food and Biotechnology and prepared by Resources for the Future, April 2003 at 39.

[6] FDA nears decision on safety in biotech wheat, Reuters 12 December 2003 http://www.genet-info.org

[7] Netherwood, T et al. Assessing the survival of transgenic plant DNA in the human gastrointestinal tract Nature Biotechnology January 18 2004.

[8] Patnaik, D. & Khurana, P. (2001) Wheat biotechnology: a mini review. EJB Electronic Journal of Biotechnology 4(2): 1-29. http://www.ejb.org/content/vol4/issue2/full/4/

[9] Patnaik, D. & Khurana, P. (2001) Wheat biotechnology: a mini review. EJB Electronic Journal of Biotechnology 4(2): 1-29. www.ejb.org/content/vol4/issue2/full/4/

[10] Repellin, A., Baga et al (2001) Genetic Enrichment of cereal crops via alien gene transfer: New challenges. Plant Cell, Tissue and Organic Culture 64: 159-183.

[11] Srivasatava, V. et al (1999) Single copy transgenic wheat generated through the resolution of complex integration patterns. Proceedings of the National Academy of Science USA 96:11117-11121.

[12] Chen, W.P. et al (1999) Development of wheat scab symptoms is delayed in transgenic wheat that constitutively expresses a thaumatin-like protein gene. Theoretical and Applied Genetics 99: 755-760.

[13] Ho, W.M., Ryan, A. & Cummins, J. (1999) Cauliflower mosaic viral promoter-A recipe for disaster*?* Microbial Ecology in Health and Disease 11:194-197. Ho, W.M., Ryan, A. & Cummins, J (1999) Hazards of transgene plants with the cauliflower mosaic viral promoter Microbial Ecology in Health and Disease 12:6-11.

[14] Section 4(1) of the Regulations to the GMO Act.

[15] Section 11(1) of the Biosafety Protocol provides as follows "A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing House. This information shall contain, at the minimum, the information specified in Annex II."

[16] http://www.monsanto.com

[17] Grain: World Markets and Trade, December 2003, http://www.fas.usda.gov/grain/circular/2003/12-03/graintoc.htm

[18] World Wheat Situation and Outlook http://www.fas.usda.gov/grain/circular/2003/12-03/wh_txt.htm

[19] World Wheat Situation and Outlook http://www.fas.usda.gov/grain/circular/2003/12-03/wh_txt.htm

[20] Cropchoice News, CropChoice.com, 2 February 2001.

[21] Egyptian Trade, Reuters, 9 February 2002.

ANNEX I Statements from North American Farmers, Farm Organizations and Civil Society Against Genetically Engineered Wheat- February, 2003

"GMO (genetically modified organism) wheat has been described as a "solution in search of a problem to solve." I tend to think of GMO wheat as a problem in search of more problems to create." Dan McGuire, Policy Chairman, American Corn Growers Association (*CropChoice News, January 24, 2003*)

"Our membership is made up of over 500 families who operate both large, modern, commercial-scale farms and smaller diversified units… The majority of our members are farmers and most are certified organic farmers. The Ecological Farmers Association of Ontario demands the following: A moratorium on any further release of GM plants, animals or other life forms, including a moratorium on the release of GM wheat. There is no support for the release of GM wheat among farmers, consumers, marketing agencies or processors." Ecological Farmers Association of Ontario Official Position (*EFAO news, Summer, 2002*)

"Elected representatives of the Agricultural Producers Association of Saskatchewan passed a resolution on June 14th (2001) to have government halt its approval of genetically modified wheat with herbicide-resistant traits. The introduction of GM wheat to Canadian fields will cause producers to lose existing conventional, identity-preserved and organic markets." Agricultural Producers Association of Saskatchewan Inc (APAS) (*Submission to the Canadian Senate, November, 2001*)

"The Canadian Health Coalition is opposed to the introduction of genetically manipulated (GM) wheat due to concerns about potential impacts on human health and inadequate regulation." Brad Duplisea, Canadian Health Coalition (*Statement to the Press, July 31, 2001*)

"…approving GE wheat in Canada would not only be a commercial disaster for the wheat industry but it would further exacerbate what is now becoming a general consensus among many, which is that this (the Canadian Parliament) is willing to go on protecting the interests of certain biotech companies at the expense of the citizens it represents." Nadege Adam, Council of Canadians (*Statement to the Press, July 31, 2001*)

"Keystone Agricultural Producers (KAP) requests that the Government of Canada, for the protection of our industry, not allow the registration and general introduction of GMO wheat varieties until the general market acceptance for this type of wheat is assured by the importing and exporting agencies involved." Don Dewar, President, Keystone Agricultural Producers. KAP represents over 5 000 individual farmers and twenty commodity groups in the province of Manitoba, Canada. (*Statement to the Press, July 31, 2001*)

"Our organization is opposed to the introduction of GM wheat based on our experience following the introduction of GM canola. In that example, cross-pollination of GM canola into the non-GM varieties led to market loss in the organic and traditional European markets. The introduction of GM wheat will result in similar problems of cross -pollination. Following the introduction of GM wheat, farmers will be faced with the choice of growing GM wheat, GM contaminated wheat, or not growing wheat. Consumers will have the option of eating products that contain Canadian GM wheat or locating wheat products manufactured from imported, GM-free wheat. These are not attractive options for farmers or consumers. The freedom of choice of farmers and consumers is dependent on GM wheat not being introduced at this time." Fred Tait, Vice-President, National Farmers Union. (*Statement to the Press, July 31, 2001*)

"The Saskatchewan Association of Rural Municipalities is here today because of concerns that the introduction and registration of genetically modified wheat in Canada would have a serious, negative impact on wheat producers." Sinclair President of ,SARM. SARM represents Saskatchewan's 297 rural municipalities. In March, 2001, SARM passed a resolution opposing the registration and introduction of GM wheat. (*Statement to the Press, July 31, 2001*)

"SOD (Saskatchewan Organic Directorate) is unequivocally opposed to any further introduction of unproven, poorly tested and regulated genetically engineered/transgenic crops, including wheat." Marc Loiselle, Saskatchewan Organic Directorate. (*Statement to the Press, July 31, 2001*)

"Roundup Ready wheat, if it is introduced, is going to be a very serious marketing problem." Shannon Storey, NFU Women's President, Saskatchewan, Canada (*Interview in Grains of Truth, Greenpeace Video, October, 2001*)

"The (US National Farmers Union) convention also adopted a policy position that supports imposing a moratorium on the introduction, certification and commercialization of genetically engineered wheat until issues of cross-pollination, liability, commodity and seed stock segregation, and market acceptance are adequately addressed." (*United States NFU Media Release, March 12, 2001*)

"Banning GM wheat is crucial to the survival of the North American farmers who grow wheat. We export most of our wheat and our foreign buyers have made it perfectly clear that they want nothing to do with genetically modified food." Terry Boehm, wheat producer from Allan, Saskatchewan, Canada and NFU Board member. (*CropChoice News, April 16, 2002*)

"Monsanto's promises simply do not match reality. We have watched foreign markets evaporate and prices fall for farmers using GM corn and soybean products and we have learned our lessons well," Bill Christison, Missouri farmer and President of the National Family Farm Coalition. (*CropChoice News, April 16, 2002*)

"We could create a train wreck in our own markets. The concerns are mounting, rather than diminishing. There are producers out there, certainly, who are clamouring for the technology. But we can't afford to (lose) 40 percent of our markets." Neil Fisher, North Dakota Wheat Commission Administrator. (*Reuters, April 29, 2001*)

"As time goes on we will not necessarily be able to guarantee that conventional varieties can remain free of genetically modified material," said Todd Leake, who grows wheat on 1,300 acres in North Dakota. (*CropChoice News, February 2, 2001*)

"If GMO wheat is introduced in the United States and cannot find a home in the export market, it may also be rejected in the domestic milling and wheat processing sector and ultimately be resisted by U.S. consumers. This would result into a situation where all that unwanted wheat will become a cheap feed grain, in direct competition with corn, thereby

forcing corn prices lower than they already are. This is a major economic issue for the farm sector, most especially corn producers," Dan McGuire, American Corn Growers Association. (*CropChoice News, July 15, 2002*)

"Loss of export markets would be a disaster for Canadian and US farmers. It would be impossible to guarantee segregation so exports would be it hard." Professor Richard Gray, Agricultural-Economist, University of Saskatchewan, Canada, (*Slice of Life, Greenpeace Video, February, 2003*)