

Comments on

Draft COMMISSION DIRECTIVE ../.../EC
of [...]

amending Council Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC and 70/458/EEC on the marketing of beet seed, fodder plant seed, cereal seed, seed-potatoes, seed of oil and fibre plants and vegetable seed and Decision 95/232/EC on the organisation of a temporary experiment in order to establish conditions to be satisfied by the seed of hybrids and varietal associations of swede rape and turnip rape
(Working document Doc.SANCO/1542/02- January 2002)

submitted by Greenpeace International

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Introduction

Greenpeace welcomes the Commission initiative to amend present seed Directives to specifically regulate the presence of genetically modified organisms (GMOs) in seeds. Contamination of conventional seed lots with GMOs has been a problem within the EU at least since 1999, especially with regard to seeds imported from the USA and Canada. This provoked varying, sometimes inadequate, reactions of member states authorities. While it is clearly illegal to release and market any GMOs not approved within the EU under the relevant EU legislation, the question of how to deal with the presence of EU approved GMOs in conventional seeds appeared unclear. Greenpeace has repeatedly pointed to this problem and supports clear, binding and effective regulations at EU level.

We thank you for the opportunity to comment on the proposed measures at an early stage and would like to contribute to what Commissioner Fischler recently demanded: "It is about time to have a consistent, efficient and complete EU legislation on GMOs." ¹

We believe such legislation should be solidly based on the precautionary principle and guided by a clear strategy to guarantee that the fundamental right of choice of consumers, farmers and citizens is respected and that the environment is protected against unnecessary risks and potentially irreversible damage.

1. General considerations

Why are GMOs different from conventional impurities of seeds?

¹ Franz Fischler, speech "Europe at the Crossroad - Finding a sustainable approach on biotechnology", Brussels, 13 February 2002

Contamination with GMOs is fundamentally different from accidental contamination with other varieties of seeds because

- ?? GMOs usually comprise genetic traits and DNA originating from organisms, which would not naturally transfer their genetic information to the transformed varieties and any of their relatives. As opposed to conventional considerations about seed purity and natural introgression of genetic traits from related plants and varieties, GMOs have the unique potential to introduce entirely new traits to certain species and their varieties.
- ?? GMOs are the result of specific and unique types of genetic modification, which are based on the introduction of new, in most cases viral, promoters, which are not typical for the regulation of the introduced genes in the original plant and seed variety.

Hence, from an environmental point of view, the introduction of the above mentioned types of genetic material into a certain variety, even at low levels, constitutes the introgression of entirely new genetic traits, regulators and DNA material into the gene-pool not only of a single variety, but of all plants, which directly or indirectly could integrate such new genetic information into their genome by outcrossing.

Lack of experience with the type of genetic modifications obtained from GMOs, including questions about the stability of GMO constructs, their ability to mutate and adapt to new environmental situations and the evolutionary fate of new promoters, requires a precautionary approach to regulate such events. Emphasis should be placed on traceability, reversibility as well as liability.

The 1% approach

When establishing its present regulation on labelling GMOs in food, the EU set a threshold of 1%, below which ingredients in food or feed need not be labelled as containing GMOs. Greenpeace supported this decision. The same threshold is now being proposed by the Commission in the draft regulation on Novel Food and Feed. Setting the 1% threshold was based on practical considerations to avoid single adventitious contamination of GMO-free products to become an insurmountable obstacle for importers of bulk commodities such as soybeans and maize and their derivatives. On the condition that no adverse health effects are to be expected from the GMOs in question, this seems to be an acceptable guarantee for consumers on the one hand and an achievable standard for the food-industry on the other.

However, when it comes to the question of the deliberate release of GMOs, which are able to reproduce and to convey their genetic information to related varieties, including wild varieties, the protection of the consumer's right to know and to choose is not the most appropriate regulatory dimension to start from. GMOs in food are no longer able to replicate in the environment, but seeds certainly are. Hence, potential effects of GMOs on the environment must be the paramount consideration for any decisions regarding the (intentional or unintentional) deliberate release of GMOs. Just as evidence or even suspicion of any adverse effects to human health would constitute a reason not to tolerate any presence of such GMOs in human food or animal feed (irrespective of any labelling thresholds), evidence or suspicion of potential adverse environmental effects should constitute a reason to prohibit any release of such GMOs into the environment. Traceability is also an important means to enable the recall of approved GMO varieties. However, if GMO contamination levels between 0,3% and 0,7% in conventional varieties were accepted, it would be nearly impossible to practically implement tracing and recall of the GMOs that caused the contamination.

Greenpeace therefore believes that known or potential environmental effects of GMOs must be the fundamental basis upon which contamination of conventional varieties with GMOs should be regulated. Greenpeace also believes that the rights of farmers as well as breeders not to use GMOs in their production must be equally protected as the consumer's right to know and to choose.

Given the present uncertainties and lack of experience, the Directive should be designed to prevent introgression of new traits and of new genetic constructs into the gene pool of the respective varieties. Initial contamination levels usually do not constitute any safe and reliable indication for potential future levels of such contamination, nor are there scientifically sound methods to quantitatively assess the fate of certain genetic traits and constructs, once released into the environment.

Scientific uncertainties require precaution

The Commission proposal strongly relies on the Opinion of the Scientific Committee on Plants¹ (SCP) concerning the adventitious presence of GM seeds in conventional seeds. This opinion repeatedly points to the present lack of available data- systematic experience and information. It also cautions that "achieving the 0.3 % and the 0.5 % thresholds will become increasingly difficult as GM crop production increases in Europe" (page. 7). This should be seen as a stark warning. Indeed, the SCP warns that "in due course the 1 % threshold [for food] set by the Commission may have to be revised." (pg. 7). This appears to apply particularly to maize and oilseed rape: "If non-GM crops of oilseed rape and maize are being grown on farms also growing a considerable proportion of GM crops of these species, and neighbouring farms are also growing GM crops, then achieving threshold levels below 1% becomes much more problematic." (pg. 9). The SCP also points to other situations where achieving the proposed seed contamination thresholds of 0.3-0.5% will be "problematic" e.g. varietal association cultivars, production of hybrid seed." (pg. 7). Furthermore, the SCP puts its statements in a general caveat: "The Scientific Committee on Plants stresses that this opinion is based on the current best scientific knowledge. This opinion may need to be revised in the light of new scientific data as it becomes available or to take into account the evolution of relevant technology." (pg.7)

In one typical case, for instance, the SCP states that "there is a lack of clear scientific data on persistence times for some species and therefore reliance is placed on anecdotal evidence and seed production experience" (pg.3) In an another paragraph it is stressed that "although the number and viability of shed seeds in soil declines over time, a very small number may persist for long periods, even for species in which the bulk of seed is short lived. This has implications for any threshold set for non-approved GM events since a level of zero volunteers cannot be guaranteed after any time interval." (pg. 12) In yet another example the Opinion states: "The figure of 0.1% GM volunteers also assumes that GE and seed crop plants have the same competitive ability, fecundity and rate of out-crossing." (pg. 11). However there are already documented cases² where genetic modification can increase competitive abilities (e.g. herbicide or insect resistance) and where even for yet to be explained reasons did increase fecundity and out-crossing rate³

Greenpeace considers this Opinion to be a classical case where those institutions responsible for risk-management (as opposed to risk-assessment which the SCP did it's best to provide)

must take a precautionary approach. The risks involved are of long term character, potentially irreversible and still not sufficiently well defined.

Zero tolerance

Against this background Greenpeace urges the Commission to introduce a general purity level for all conventional seeds not labelled as containing GMOs at the present detection level of 0,1%, for both approved and unapproved GMO events.

This is the only rationale measure to:

- ?? Protect the European consumer's right to know and to chose not to eat GMOs in the long run;
- ?? Protect all European farmers rights not to use GMOs in their agricultural practice, including their own breeding and reproduction of seeds;
- ?? Protect breeders rights not to use GMOs in their products and to keep their lines free of transgenic genetic material, not naturally occurring in the respective species, crops and varieties;
- ?? Prevent increasing contamination of seeds with GMOs;
- ?? Protect the natural genetic diversity and integrity of the gene-pool of crops and varieties affected, ensuring long term availability of pure varieties and thus the rights of future generations;
- ?? Enable a practically feasible and long term viable system of traceability, control and liability at the root of the food chain;
- ?? Deal with present scientific and practical uncertainties, regarding inter alia outcrossing potential both with related cultivated and wild relatives, volunteer management, persistence of seeds, potentially increased reproduction and outcrossing rates of GMOs;
- ?? Cautiously deal with the presently small and unreliable scientific and empirical data basis for calculations on how to maintain the threshold of 1% for contamination in non-labelled food;
- ?? Implement a precautionary approach in protecting the fundamental basis of food in Europe and world-wide and
- ?? Reflect the overwhelming majority of European Citizens' demand not to have GMOs in their food and environment.

Present situation of contamination

Over the past years member state authorities, as well as companies, have conducted thousands of PCR tests on seeds and found only sporadic contamination levels above 0,1%, both of approved and unapproved GMO varieties. On March 5th the French Ministry for Economy, Finance and Industry- DGCCRF published results of 132 seed tests of maize, soya and swede rape seed conducted in France in 2001/2002, which detected only a single case of contamination (at a level of 0,2%)⁴ Similar results have been obtained for instance by German⁵ and Austrian⁶ authorities. The French result is particularly interesting as the contamination results in 2000/2001 had been well above this level.

Major producers and retailers⁷ in Europe, whom Greenpeace has worked with in order to source GMO-free ingredients, have set up non-GMO food ingredient chains that consistently achieve 0.1% thresholds in practice, even though the labelling threshold for their products is

set at 1%. This is often obtained within their own quality management system or with the use of 3rd party certification (e.g. CERT-ID). These systems are in place for bulk volumes, and over a wide range of products and ingredients. The companies ask their suppliers to `aim for zero`, and in practice they specify that 0.1% (detection level), is the point at which the product or ingredient is rejected.

Furthermore, in January Greenpeace put forward a list of more than 30 US companies committed to providing GMO-free seeds under 0.1% threshold of contamination, even within the USA, where GMO contamination levels of conventional seeds are neither specifically regulated nor systematically monitored and controlled.⁸

This shows that seed producers are perfectly able to fulfil the 0,1% standard where the markets clearly demand it; the above mentioned systems would obviously be in jeopardy, if the thresholds suggested by the Commission were to be implemented.

Effects of market concentration

Greenpeace also perceives the present discussions about achievable levels of seed purity regarding GMOs as a matter of political will and leadership. If the Commission introduces strict protection levels at this point, companies producing and marketing GMOs will have to adapt to these standards as they have done in innumerable other cases of product regulation. However, as in most of those past cases, industry will always argue that measures were too strict, not feasible and economically not viable. Over the years a certain culture of bargaining about thresholds and protection levels have developed, and this has sometimes worked well to achieve improving standards of environmental and health protection and best available technologies. These examples, however, dealt usually with emission levels of non-reproductive material, aiming at their gradual reduction. But, in the case of seeds we are dealing with a situation where initial contamination levels can easily multiply and accumulate over the years and decades, carrying a substantial risk of getting out of control in certain cases. At the same time, GMO contamination levels of seeds in Europe are still minimal, and massive contamination can still be controlled and prevented effectively.

Unfortunately, test results and data from companies who conduct most of the tests are usually confidential business information, which is not publicly available. This is especially true for seed companies also producing GMOs and strongly promoting their use. As the global and European seed market underwent a spectacular process of concentration over the past two decades, the position of less than 10 companies is decisive for the market¹. A small number of these major seed companies, who dominate the European and global market of some major crop seeds, are also producing GMOs, and thus have a vested interest in the issue. It is these companies, and the professional associations they dominate, who consistently claim that a certain level of GMO contamination is inevitable. They argue that this has to be accepted as "a fact of nature" and hence needs to be legalised at a threshold level much higher than technically necessary. These companies also perceive the entire system of traceability and control as discriminating against their GMO products and argue that they are not different from conventional seeds, among which a certain level of genetic exchange is constantly ongoing.

¹: Monsanto, Syngenta, Aventis, DuPont/ Pioneer, Advanta, Dow, Limagrain, KWS.

In this situation the Commission and Member States' governments have to take a firm position, defending the rights and the will of European citizens, consumers, farmers and breeders against the strong market position of the industry. The EU has the duty to prevent entering a vicious circle of adapting contamination levels to the realities these companies shape. Interested companies could, by negligence or even intentionally, induce a certain level of seed contamination, which could be sufficient to continually introduce GMOs in most conventional seed varieties - and from there up the food chain and on to wild relatives - at an accumulating pace. Once such introgression of the GMO events into breeding material and the commercial seeds available has started it would be extremely difficult, costly and cumbersome to reverse this situation. The industry's argument that GMOs are out and hence must be accepted could thus become a self-fulfilling prophecy. Regulators would soon be in a situation, where even present purity levels for food, as well as seeds, would be threatened.

"The real strategy", The UK Guardian newspaper wrote last year, "is to introduce so much genetic pollution that meeting the consumer demand for GMO-free food is seen as not possible. The idea, quite simply, is to pollute faster than countries can legislate - then change the laws to fit the contamination"⁹ Greenpeace hopes that the Commission will effectively prevent such a strategy, should it exist.

2. Considerations regarding the implementation

The Directives on seed marketing to be amended do not provide for the regulation of liability cases that would inevitably arise from the obligations imposed by this Directive. This creates a major dilemma, which should be resolved by appropriate additional legislation before implementation of this Directive.

Greenpeace expects the Commission to apply the "polluter pays" principle, enshrined in the EU Treaty, also in this case. However at this point there is no legal guarantee that the producers - and in certain cases also users - of GMOs are legally obliged to prevent and eventually compensate for any contamination of conventional seeds which they would cause. In practice, in some cases it may also prove difficult to unquestionably identify the causative party of such contamination .

Under these circumstances, the obligations set for seed producers would unduly put the burden of costs and additional measures necessary to conform with this Directive on breeders and farmers, who do not want to use GMOs in their products. While multinational and large national seed companies can be more flexible in their choice of the areas of research and reproduction, small breeders - and especially farmers either reproducing seeds for such companies or reproducing their own seed material - cannot shift their planting areas with comparable flexibility. Hence the Directive could set unfair competitive conditions with unwanted effects. Indeed; it could even prevent the free choice of practise for certain farmers, unless legal conditions beyond the same Directive would effectively protect them.

Unfortunately, the Commission's recent proposal for a Directive on Environmental Liability so far is not designed to tackle this problem effectively, and does not provide for commercial liability between civil parties.

Given the short comment period, this paper cannot go into all the details of this legal question. However, Greenpeace is firmly convinced that farmers should not incur additional costs for producing non-GM seeds and crops. The costs of monitoring and additional measures (farming practices) where necessary to avoid GMO contamination should be borne by the

industry producing the GMOs, or, in particular circumstances, by the farmers using such GMOs. Effective rules and legislation should be urgently established in order to clearly identify who should be responsible for enforcing preventive and monitoring measures and farming practices, and who should pay if they are not - or not correctly - implemented. In the case of GMO contamination, strict liability should apply to the relevant GMO industry. As for the farmers, fault-based liability should apply to the owners of GM crops in cases of negligence in the implementation of the relevant measures to avoid contamination. A system of penalties should be enforced in case of infringement of those measures. In no circumstances should additional costs to avoid genetic contamination, or economic loss due to contamination, be borne by those farmers and breeders who have not planted GMOs.¹

3. Remarks on specific points of the draft Directive

1. Greenpeace suggests to avoid the term "technically unavoidable" as this suggests an irresolvable dilemma, which in reality does not exist.
2. The draft Directive makes a reference to the "intention of the Commission to propose to amend Directive 2001/18". This intention has been formalised in the proposal for a GM Food and Feed Regulation, which was presented by the Commission on July 25, 2001, and is now before the Council and the European Parliament for the first reading. However, the article amending Directive 2001/18 could be rejected during the legislative co-decision process, and the Seed Directive cannot pre-empt now the final result of that process.
3. The draft Directive makes reference to "the protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seed as laid down in Commission Regulation (EC) N° ./...". No such protocol or draft of it today seems to be publicly available for comment. However this Regulation would be a pivotal part of the proposed Directive.
4. A proposed additional section 8 under Annexes I of the present Directives mentions " (...) the possible establishment and monitoring of areas for seed production for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown." Greenpeace is of the opinion that an official division between "GMO-zones" and "GMO free zones" could jeopardise the rights of breeders and farmers in "GMO-zones" substantially. While we welcome local initiatives regarding the protection of natural diversity, we consider it a fundamental right of all farmers anywhere within the EU to grow and reproduce seeds without GMO contamination.

¹ The short minutes of the Standing Committee on Seed and Propagating Material for Agriculture, Horticulture and Forestry, as available on the Commissions web-site, indicate that similar concerns have been raised by representatives of various Member States during discussion of this issue. On February 22 and 23, 2001, "various member States" underlined that "the liability implications needed to be clarified". They also noted that the Commission plan "did not address the questions of penalties applicable to infringements". On July 4, 2001, among the "points which would need further consideration", national delegations raised "the problem of liability in the case of non-compliance" and the "increasing of the price of conventional seed". On September 13 and 14, 2001, "some member States asked that the obligations should not be only be put on the production of non-GM seeds, but also on the production of GM seeds". And on February 7 and 8, 2002, some delegations raised the point of "the impact on seed production practices and on the increasing costs of conventional seed".

5. Notwithstanding our argument for a general threshold at detection level of 0,1%, the Commission's conclusions regarding the proposed 0,5% threshold for maize appear inconsistent with the recommendations and calculations of the Scientific Committees Opinion, which clearly states that "A threshold of 1% can be achieved with 0.3% GM adventitious presence in seed sown if good management practices are adhered to. However, if non-GM crops of oilseed rape and maize are being grown on farms also growing a considerable proportion of GM crops of these species, and neighbouring farms are also growing GM crops, then achieving threshold levels below 1% becomes much more problematic." " (pg. 9) The Commission's change from it's initial suggestion of 0,3% (as proposed to the Committee) to now 0,5% is not justified by the Committee's recommendations.
6. Would "best practice" of volunteer control, as referred to in the Committee's Opinion include the use of herbicides? If so, what would be the recommendations to organic farmers?
7. Article 5, paragraph 3 (h) of Council Regulation (EEC)No 2092/91of 24 June 1991 on organic production of agricultural products and indications requires that a product labelled as organic "has been produced without the use of genetically modified organisms and/or any products derived from such organisms." Is the Commission of the opinion that simple adherence to the requirements laid down in this draft Directive, which would allow for up to 0,7% of GMO seed contamination, still fulfil the requirements of regulation2092/91?
8. The scope of the proposed Directive is limited to those species, which have been genetically modified and are cultivated in the EU. However, as other species are presently being genetically modified, which are also grown within the EU (e.g. wheat), appropriate provisions should be made to regulate seed production of such species before they are commercially available in other parts of the world (and thus pose a risk of also being introduced into the EU).
9. While testing for GMO events approved within the EU may be a standard procedure, testing for contamination with unapproved varieties depends on the availability of appropriate reference material and primers for PCR. How does the Commission suggest coping with the potentially increasing number of such events and their detection?
10. Approval of a GMO under Directive 2001/18 does not automatically imply approval for commercialisation of varieties containing such a GMO event. Registration in national and European Seed Registers could be rejected for agronomic or other reasons. This leads to situations where approved varieties as defined in the proposed Directive could still be prohibited from marketing. It appears inconsistent with the Community legislation that contamination with such varieties would be accepted under the proposed Directive at comparatively high levels.

¹ SCIENTIFIC COMMITTEE ON PLANTS SCP/GMO-SEED-CONT/002-FINAL 13 March 2001, Opinion of the Scientific Committee on Plants concerning the adventitious presence of GM seeds in conventional seeds. (Opinion adopted by the Committee on 7 March 2001). All subsequent quotations with reference to a page number (pg.) are referring to this document.

² Stewart, C.N., All, J.N., Raymer, P.L. & Ramachandran, S (1997) Increased fitness of transgenic insecticidal rapeseed under insect selection pressure. *Molecular Ecology*, **6**, 773-779.

³ Belgelson, J., Purrington, C.B. & Wichmann, G. (1998) Promiscuity in transgenic plants. *Nature*, 396, 25.

⁴ Ministère de l'Économie, des Finances et de l'Industrie - DGCCRF - 05 mars 2002, OGM, Bilan des contrôles réalisés par la DGCCRF, present reference http://www.industrie.gouv.fr/infopres/comm/f2i_dern.htm

⁵ Information requested by Greenpeace from German States (Bundeslaender) under Council Directive 90/313/EEC on the Freedom of Access to Information on the Environment, available from Greenpeace

⁶ Written answer of the Ministry of Agriculture to questions of MPs Pircklhuber, Glawischnik and friends regarding contamination of seeds as of 02.07.2001, 2494/AB XXI.GP, 2493/J XXI.GP, available from Greenpeace

⁷ For confirmation an further information contact for instance: Tesco - Tonny Plamer - Senior Technical Manager, Tony.j.palmer@uk.tesco.com; Sainsburys - Raechel Wilson - Technical & Communications Dept. raechel.wilson@sainsburys.co.uk; Co-op - David Croft - Head of Quality and Consumer Care, david.croft@co-op.co.uk; as an example for third party certification at 0.1% see <http://www.genetic-id.com>

⁸ The list, which includes maize, cotton and soybean seeds, has been established by CropChoice, a US farm information bureau and can be found at <http://www.cropchoice.com>

⁹ The Guardian, January 21, 2001, page 18, "When choice becomes just a memory"