IN THE MATTER OF CO-EXISTENCE,
TRACEABILITY AND LABELLING OF GMOS

ADVICE

INTRODUCTION

1. We have been asked to advise Friends of the Earth, Greenpeace, the Consumer Association and the Soil Association in relation to particular issues arising from Directive 2001/18/EC (on the deliberate release into the environment of genetically modified organisms – "GMOs"), Regulation (EC) No. 1829/2003 (on genetically modified food and feed) and Regulation (EC) No. 1830/2003 (concerning the traceability of food and feed products produced from genetically modified organisms). We are asked to advise principally in relation to the following:

   (i) the nature and breadth of the Member States' discretion (or obligation) in establishing any "co-existence" regime under Article 26a(1) of Directive 2001/18/EC ("the Directive") and the objectives which a Member State may or must have in mind when creating such a regime;

   (ii) the effect on the labelling requirements of Regulation 1829/2003 of establishing a regime under Article 26a(1) which aims to establish a base-line threshold of 0.9% GM content;

   (iii) the requirements of Regulation 2092/91 "on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs" ("the Organic Regulation") in relation to GM and the effect of permitting a base-line threshold under Article 26a(1) measures; and

   (iv) the status of the Commission Recommendation of 23 July 2003 "on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming" ("the Co-existence

Recommendation") and the legal correctness of the approach taken therein to base-line thresholds.

2. Before addressing those issues, we think it is necessary and convenient to explore the legislative context.

LEGISLATIVE CONTEXT

The requirement for authorisation

3. The Directive (which is a legislative instrument binding only on Member States and providing a legislative framework according to which certain results are required to be achieved) has the objective, in accordance with the precautionary principle, of approximating the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when:

   - carrying out the deliberate release into the environment of GMOs for any other purposes than placing on the market within the Community, and
   - placing GMOs on the market as or in products within the Community[1].

4. There is a general obligation upon Member States to ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs. GMOs may only be deliberately released or placed on the market in conformity with the Directive[2].

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[1] Article 1

[2] Article 4

5. A clear objective of the Directive is the protection of the environment and human health. That objective is also enshrined in the EC Treaty in Articles 6 and 152, although the Directive itself is based specifically on Article 95.

6. The Directive establishes a system of authorisation for the release of GMOs with different but parallel provisions applying respectively to GMO release where such release is for some purpose other than marketing and to GMO release where GMOs are to be marketed as or contained in products. In either case, subject to limited exceptions, a release may take place only with and subject to the conditions of an authorisation by EC legislation or from the competent authority of a Member State. An authorisation has effect throughout the Community.

7. It follows therefore that Community law does not permit of any tolerance in relation to GMO content where the relevant GMO has not been authorised. For example, Article 4(5) of the Directive (which covers the general obligations imposed on Member States) provides that, in the event of an unauthorised release, the release must be "terminated". The ordinary meaning of such an obligation is that the release must be stopped in its entirety, not stopped in part only or reduced in volume. The only circumstance in which unauthorised GMO content is tolerated is by virtue of transitional measures whereby authorisation is not required for adventitious or technically unavoidable trace elements of GMO to a threshold of 0.5%, where an application for authorisation in relation to that GMO has reached a certain stage in the process of consideration and certain stringent conditions have been met[3].

Labelling

8. The Directive also provides for the continued monitoring of GMO products for their potential effects on human health or the environment. To that end, the Directive seeks to ensure traceability of GMOs at all stages of the placing onto the

[3] Article 12a (inserted by Regulation 1829/2003)

market of products in which they are contained. With that in mind, Article 21 therefore provides for labelling and packaging of GMO products and provides:

"1. Member States shall take all necessary measures to ensure that at all stages of the placing on the market, the labelling and packaging of GMOs placed on the market as or in products comply with the relevant requirements specified in the written consent referred to in Articles 15(3), 17(5) and (8), 18(2) and 19(3).

2. For products where adventitious or technically unavoidable traces of authorised GMOs cannot be excluded, a minimum threshold may be established below which these products shall not have to be labelled according to the provision in paragraph 1. The threshold levels shall be established according to the product concerned, under the procedure laid down in Article 30(2).

3. For products intended for direct processing, paragraph 1 shall not apply to traces of authorised GMOs in a proportion no higher than 0,9 % or lower thresholds established under the provisions of Article 30(2), provided that these traces are adventitious or technically unavoidable."

9. Article 21 therefore imposes an obligation to label authorised GMOs and product with authorised GM content. It recognises however that there may be situations in which adventitious and technically unavoidable traces of authorised GMO cannot be excluded. In such circumstances, and only in such circumstances, there is an exception to the general obligation to label GM products where the technically unavoidable or adventitious content is lower than a specified threshold. In relation to products intended for direct processing, that threshold has been set at 0.9%. That threshold derives from an amendment to the Directive made by Regulation No. 1830/2003.

10. Regulations No. 1829/2003 and No. 1830/2003 apply a special regime to food and feed containing, consisting of or produced from GMOs. Regulations differ from Directives in that they are binding in their entirety, are directly applicable in Member States and bind individuals and companies as well as Member States. Regulation No. 1829/2003 establishes rules for the authorisation, supervision and labelling of GM food and feed which are applicable to such food and feed irrespective of whether or not they contain products which have previously received an authorisation pursuant to Directive 2001/18. The objectives of the Regulation are found in its Recitals, *inter alia,* as follows:

"*(1) The free movement of safe and wholesome food and feed is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.*
(2) A high level of protection of human life and health should be ensured in the pursuit of Community policies.
(3) In order to protect human and animal health, food and feed consisting of, containing or produced from genetically modified organisms (hereinafter referred to as genetically modified food and feed) should undergo a safety assessment through a Community procedure before being placed on the market within the Community."

11. With regard to labelling, the recitals to the Regulation provide:

"(17) In accordance with Article 153 of the Treaty, the Community is to contribute to promoting the right of consumers to information. In addition to other types of information to the public provided for in this Regulation, the labelling of products enables the consumer to make an informed choice and facilitates fairness of transactions between seller and purchaser.
(18) Article 2 of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs provides that labelling must not mislead the purchaser as to the characteristics of the foodstuff and among other things, in particular, as to its nature, identity, properties, composition, method of production and manufacturing….
(20) Harmonised labelling requirements should be laid down for genetically modified feed to provide final users, in particular livestock farmers, with accurate information on the composition and properties of feed, thereby enabling the user to make an informed choice.
(21) The labelling should include objective information to the effect that a food or feed consists of, contains or is produced from GMOs. Clear labelling, ***irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product****, meets the demands expressed in numerous surveys by a large majority of consumers, facilitates informed choice and precludes potential misleading of consumers as regards methods of manufacture or production.*
(22) In addition, the labelling should give information about any characteristic or property which renders a food or feed different from its conventional counterpart with respect to composition, nutritional value or nutritional effects, intended use of the food or feed and health implications for certain sections of the population, as well as any characteristic or property which gives rise to ethical or religious concerns.
(23) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC(16) ensures that relevant information concerning any genetic modification is available at each stage of the placing on the market of GMOs and food and feed produced therefrom and should thereby facilitate accurate labelling.
(24) ***Despite the fact that some operators avoid using genetically modified food and feed, such material may be present in minute traces in conventional food***

and feed as a result of adventitious or technically unavoidable presence during seed production, cultivation, harvest, transport or processing. In such cases, this food or feed should not be subject to the labelling requirements of this Regulation. In order to achieve this objective, a threshold should be established for the adventitious or technically unavoidable presence of genetically modified material in foods or feed, both when the marketing of such material is authorised in the Community and when this presence is tolerated by virtue of this Regulation.

(25) It is appropriate to provide that, when the combined level of adventitious or technically unavoidable presence of genetically modified materials in a food or feed or in one of its components is higher than the set threshold, such presence should be indicated in accordance with this Regulation and that detailed provisions should be adopted for its implementation. The possibility of establishing lower thresholds, in particular for foods and feed containing or consisting of GMOs or in order to take into account advances in science and technology, should be provided for.

(26) It is indispensable that operators strive to avoid any accidental presence of genetically modified material not authorised under Community legislation in food or feed. However, in order to ensure the practicability and feasibility of this Regulation, a specific threshold, with the possibility of establishing lower levels in particular for GMOs sold directly to the final consumer, should be established as a transitional measure for minute traces in food or feed of this genetically modified material, where the presence of such material is adventitious or technically unavoidable and provided that all specific conditions set in this Regulation are met. Directive 2001/18/EC should be amended accordingly. The application of this measure should be reviewed in the context of the general review of the implementation of this Regulation.

(27) In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to demonstrate to the competent authorities that they have taken appropriate steps to avoid the presence of the genetically modified food or feed.

12. The Regulation itself makes, *inter alia*, the following provision for the labelling of GM food in Article 12:

"1. This Section shall apply to foods which are to be delivered as such to the final consumer or mass caterers in the Community and which:
(a) contain or consist of GMOs; or
(b) are produced from or contain ingredients produced from GMOs.

2. This Section shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.

3. In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to

satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such material.

4. Appropriate lower thresholds may be established in accordance with the procedure referred to in Article 35(2) in particular in respect of foods containing or consisting of GMOs or in order to take into account advances in science and technology."

13. Parallel provisions apply in relation to GM feed.

14. Again, therefore, the precondition for the exclusion from the general obligation to label products with GM content is that the content is adventitious or technically unavoidable. The burden of proving that GM content is "adventitious or technically unavoidable" lies firmly with operators, which are defined in the Regulation as "the natural or legal person responsible for ensuring that the requirements of this Regulation are met within the food businesses or feed businesses under its control".

Coexistence

15. Article 43(2) of Regulation 1829/2003 amends the Directive by inserting Article 26a. It provides:

"Measures to avoid the unintended presence of GMOs
1. Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.
2. The Commission shall gather and coordinate information based on studies at Community and national level, observe the developments regarding coexistence in the Member States and, on the basis of the information and observations, develop guidelines on the coexistence of genetically modified, conventional and organic crops."

16. It is this provision which forms the basis of the UK government's actions on co-existence. The government's position concerning the scope of its discretion under Article 26a has been set out most recently in Linda Smith's letter of 5 August 2004 to Friends of the Earth.

17. She states:

"…Member States do not have a free hand to take measures aimed at achieving a threshold or thresholds lower than those determined at EU level…. Directive 2001/18 and Regulations 1829/2003 and 1830/2003 must be read together….."

18. She also states that the objective of coexistence measures is an economic matter and that the objectives of avoiding harm to the environment and/or human health are addressed by the risk assessment and authorisation processes of the Directive.

19. This accords with the approach of the Commission in its Coexistence Recommendation which states:

"Since only authorised GMOs can be cultivated in the EU (1), and the environmental and health aspects are already covered by Directive 2001/18/EC, the pending issues still to be addressed in the context of coexistence concern the economic aspects associated with the admixture of GM and non-GM crops".

20. We consider that both the approach of the UK government and that of the Commission Recommendation have no basis in Community legislation and are wrong in law.

THE SCOPE OF THE MEMBER STATE'S DISCRETION UNDER ARTICLE 26A: IS IT LIMITED BY REFERENCE TO LABELLING THRESHOLDS?

21. The origin of Article 26a lies in Regulation No. 1829/2003. Recital 28 to the Regulation provides:

> "(28) Operators should avoid the unintended presence of GMOs in other products. The Commission should gather information and develop on this basis guidelines on the coexistence of genetically modified, conventional and organic crops. Moreover, the Commission is invited to bring forward, as soon as possible, any further necessary proposal."

22. This, in our view, is distinct from the subject matter of recitals 24 to 27. Those recitals refer to the adventitious or technically unavoidable presence of GMOs in food or feed in a number of different situations. Recital 26, for example, refers to the accidental presence of unauthorised GMOs in food or feed. Recitals 24-25 appear to refer to the presence of authorised GMOs.

23. Recital 28 departs from the phraseology of recitals 24-27 by referring simply to the "unintended" presence of GMOs in "other products". It is obviously correct to point out that the word "adventitious" in the earlier recitals overlaps in meaning with the word "unintended", although the word "technically unavoidable" does not necessarily do so. It is also correct to point out that the phrase "other products" could be construed as referring to "products other than GMOs" or "products other than food or feed".

24. However, taking things in context, we consider that, whereas recitals 24-27 are concerned with tackling the situation that arises when there is an adventitious or technically unavoidable presence of GMOs in food or feed, recital 28 and, accordingly, Article 26a are concerned with securing coexistence, that is, the prevention of (unintentional) "contamination" of products other than GM products. Recital 28 and Article 26a therefore concern a situation that logically precedes the situation considered by recitals 24-27.

25. The labelling thresholds are therefore legally irrelevant so far as the scope of co-existence measures is concerned. Further, it cannot be said that the only objective of coexistence measures, as envisaged in Article 26a, is the economic protection of non-GM producers.

26. In relation to the first point made in the preceding paragraph, we are of the clear view that appropriate measures to avoid GM presence in non-GM products, taken pursuant to Article 26a, are not as a matter of law constrained by the labelling thresholds. There is nothing in the wording of the Directive or Regulation 1829/2003 to support such a limitation. Moreover, there is no canon of construction or legislative rationale dictating or leading to such an interpretation. Indeed it is strongly arguable that the structure of the legislation would indicate that a limitation on the scope of "appropriate" coexistence measures by reference to labelling thresholds would be illogical.

27. To begin with, Article 26a refers clearly and simply to measures to "avoid the unintended presence of GMOs". As a matter of ordinary language and

commonsense, measures that permitted a certain level of GM content would not "avoid the unintended presence of GMOs".

28. From the policy perspective, coexistence means the ability of farmers to make a practical choice between conventional, organic and GM crop production. Measures that permitted a certain level of GM content could not be said to be directed at enabling farmers to make such a choice.

29. Further, as stated above, there are two relevant conditions for the exclusion from the general obligation to label products with GM content: (i) the content must be adventitious or technically unavoidable; and (ii) it must be below the threshold. Coexistence measures that established a regime that aimed to do no more than limit GM content in products not intended to be GM to a 0.9% threshold would therefore be meaningless, so far as the labelling requirements are concerned, unless the operator was also able to satisfy the additional requirement for the labelling exemption, namely, that the GM presence was adventitious or technically unavoidable.

30. Finally, if one aim of co-existence measures is to provide economic protection for non-GM operators, whilst accepting the legitimacy of authorised GM production, the placing upon the scope of such measures of the limitation of achieving a base-line norm of 0.9% (rather than achieving lower levels of, or the avoidance altogether of, contamination) arguably renders it practically more difficult for non-GM operators to ensure that they benefit from the labelling exemption.

31. By contrast, a regime that sets out to prevent cross-contamination, as far as is technically possible, renders it easier for non-GM producers to comply with all elements of the labelling exemption. Limiting such a regime by reference to a base-line tolerance could also preclude the ability of non-GM operators to establish a GM-free labelling regime akin to the organic labelling regime, to which we return below.

32. As indicated above, it seems to us that the concept of coexistence measures is crucially relevant: they are directed towards preventing the avoidable

contamination of non-GM produce and not to merely minimising such contamination to (acceptable) tolerance levels.

33. In summary, therefore, there is no legislative provision which requires the Member State to limit its coexistence measures to go no further than is necessary in order to ensure that GM content stays below the Community's labelling threshold. Nor is there any compelling practical or other reason to construe the scope of "appropriate measures" as containing such a limitation.

THE SCOPE OF THE MEMBER STATE'S DISCRETION UNDER ARTICLE 26A: IS IT LIMITED BY REFERENCE TO ECONOMIC CONCERNS?

34. The short answer is no. Although we would accept that, in the Recommendation, it is stated that "Coexistence is…concerned with the potential *economic impact* of the admixture of GM and non-GM crops" (original emphasis), the Recommendation also goes on to say: "Since only authorised GMOs can be cultivated in the EU, and the environmental health aspects are already covered by Directive 2001/18/EC, the pending issues still to be addressed in the context of coexistence concern the *economic* aspects associated with the admixture of GM and non-GM crops" (original emphasis). In that respect, it is significant that Article 26a was introduced by Regulation No. 1829/2003 into the Directive which, as the Recommendation states, is concerned with environmental and health aspects of GM. That implies that Article 26a was not intended to be limited in scope to the economic aspects of coexistence.

35. Further, in our view, the Member States are required by virtue of Articles 1 and 4 of the Directive and Articles 6 and 152 of the EC Treaty to take into account the aims of protection of human health and the environment in implementation of Community law. Further, Articles 1 and 4 of the Directive require that the precautionary principle informs implementation of the Directive's provisions.

36. We do not consider the argument that all concerns relating to human health and the environment are satisfied during the authorisation stage, such that they play no part in the context of appropriate measures under Article 26a, to be a tenable one.

Although there is an environmental risk assessment undertaken during the process of authorisation, the Directive and Regulations themselves recognise a continuing need to protect health and the environment. To that end, the Directive provides for continuing monitoring requirements[4] and a safeguard clause to suspend and withdraw GM products[5]. The principal aim of the labelling requirements, apart from being to inform consumer choice, is to enable the proper monitoring of GM and to take appropriate safeguard measures. That is confirmed by the Recitals to Regulation 1830/2003:

> "***(3) Traceability requirements for GMOs should facilitate both the withdrawal of products where unforeseen adverse effects on human health, animal health or the environment, including ecosystems, are established, and the targeting of monitoring to examine potential effects on, in particular, the environment. Traceability should also facilitate the implementation of risk management measures in accordance with the precautionary principle***.
>
> *(4) Traceability requirements for food and feed produced from GMOs should be established to facilitate accurate labelling of such products, in accordance with the requirements of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed(6), so as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner as well as to enable control and verification of labelling claims. Requirements for food and feed produced from GMOs should be similar in order to avoid discontinuity of information in cases of change in end use."*

37. The protection of human health and the environment is therefore, of necessity, a continuing aim of the Community legislation and, therefore, an aim of Article 26a, and is not discharged entirely by the authorisation process. The question arises whether Article 26a measures which have the aim of permitting a base-line norm of a 0.9% tolerance across the board would be consistent with that aim, and the precautionary principle. We think not.

CONCLUSION AS TO QUESTION (i)

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[4] Article 20

[5] Article 23

38. We are inclined to the view that:

    (i) the scope of the Member State's power to adopt appropriate co-existence measures under Article 26a is not constrained as a matter of legal construction to adopting measures which go no further than achieving the labelling thresholds found elsewhere in the relevant legislation; and

    (ii) the objectives of such coexistence measures are not restricted to considerations of an economic nature: indeed the Member State is required to have regard to the aims of protecting human health and the environment in adopting any such measures.

THE EFFECT ON THE LABELLING REQUIREMENTS OF ESTABLISHING A COEXISTENCE REGIME WHICH AIMS TO ESTABLISH A BASE-LINE THRESHOLD OF 0.9% GM CONTENT.

39. The answer to this question is in our view dependant on the meaning of the "adventitious or technically unavoidable" requirement in the relevant labelling provisions. The evidential requirements contained, *inter alia*, in Article 12 of Regulation 1829/2003 already assume that such accidental or technically unavoidable presence is unintended since operators must show the steps taken to avoid such presence. As a matter of ordinary language and legislative interpretation, therefore, the terms "adventitious or technically unavoidable" clearly go beyond mere unintentional presence.

40. The terms "adventitious" and "technically unavoidable" are not defined in the relevant legislation. They are clearly separate concepts, either of which may be satisfied in order to exercise the labelling exemption. "Adventitious" is defined in the Oxford English Dictionary as:

    "Coming from without, accidental, causal."

41. It seems to us that adventitious in this context means accidental and arising from outside the process, or non-inherent. Some support for that proposition, if needed, is derived from Commission Regulation (EEC) No 1470/68 of the Commission on

the drawing and reduction of samples and the determination of the oil content, impurities and moisture in oil seeds. Article 2.3 provides:

> "Special care is necessary to ensure that all sampling apparatus is clean, dry and free from foreign odours.
> Sampling should be carried out in such a manner as to protect the samples of oilseeds, the sampling apparatus and the containers in which the samples are placed from ***adventitious contamination such as rain, dust***, etc."

42. It would seem to us to be strongly arguable that GM presence which is "built-in" or inherent by virtue of a generally applicable base-line norm or tolerance does not accord with the definition of adventitious presence.

43. As regards GM presence that is "technically unavoidable", we consider that term to introduce an absolute requirement (since it is not tempered by any reference to "reasonable" or any further qualification) that the GM presence is a result of the objective impossibility of avoiding GM content by technical methods. In our view, "technically unavoidable" presence would also exclude presence arising systemically where GM content could in fact technically be avoided. It is not a subjective test confined to the circumstances of each case. What is in fact objectively technically unavoidable on the basis of available techniques is a matter for scientific assessment.

44. Thus, in our view, the labelling exemption applies only to products with a GM content which is essentially accidental and non-inherent (though it may be technically avoidable) or to products with a GM content which is not accidental and is inherent but cannot technically be avoided. A co-existence regime which aims to establish a base-line threshold of 0.9% GM content across the board would, we consider, generally preclude any reliance in practice by operators on the exemption for "adventitious" presence below that threshold if an element of GM content became inherent in all products.

45. It would seem to us that whether or not the labelling exemption could apply at all in such circumstances depends on whether, as a matter of fact, the GM presence is objectively technically avoidable. Reliance by the operator on any base-line

threshold resulting from co-existence measures would not in our mind be sufficient to discharge the burden placed upon him to demonstrate that the presence was "technically unavoidable".

CONLUSION AS TO QUESTION (i)

46. In conclusion, therefore, we are inclined to the view that a co-existence regime which aims to establish a base-line threshold of 0.9% GM content across the board would considerably reduce the scope, if not eliminate the possibility, of operators relying on the "adventitious" exception and would not absolve the operators from demonstrating "technically unavoidable" GM presence in order to benefit from the labelling exemption.

THE ORGANIC REGULATION

47. Article 1 of the Regulation provides, *inter alia*:

"1. This Regulation shall apply to the following products, where such products bear, or are intended to bear, indications referring to the organic production method:
(a) unprocessed agricultural crop products; also livestock and unprocessed livestock products, to the extent that principles of production and specific inspection rules for them are introduced in Annexes I and III;
(b) processed agricultural crop and livestock products intended for human consumption prepared essentially from one or more ingredients of plant and/or animal origin……."

48. As regards labelling as organic, Article 5(1) relates to unprocessed products and provides that the labelling and advertising of a product specified in Article 1(1) (a) may refer to organic production methods only where certain cumulative conditions are met, one being that:

"the product was produced in accordance with the rules laid down in Article 6 or imported from a third country under the arrangements laid down in Article 11".

49. Article 6(1)(d) provides:

"genetically modified organisms and/or any product derived from such organisms must not be used, with the exception of veterinary medicinal products."

50. Article 5(3) similarly provides in relation to processed products that the organic label may be applied only where:

> "the product has been produced without the use of genetically modified organisms and/or any products derived from such organisms".

51. The "use of GMO and GMO derivatives" is defined in Article 4 as the:

> "use thereof as foodstuffs, food ingredients (including additives and flavourings), processing aids (including extraction solvents), feedingstuffs, compound feedingstuffs, feed materials, feed additives, processing aids for feedingstuffs, certain products used in animal nutrition (under Directive 82/471/EEC) (6), plant protection products, veterinary medicinal products, fertilisers, soil conditioners, seeds, vegetative reproductive material and livestock".

52. We consider that, as a matter of ordinary language "must not be used" and "without the use of" refers to both active and passive (or unconscious or unintentional) use: use in this context extends therefore to *de facto* use. It is tantamount to saying that the product must not contain that substance. We are firmly of the view, therefore, that the Organic Regulation provides that, in order to be labelled or referred to as organic, a product must not contain GMOs or GM derivatives in whatever quantity. It does not therefore permit of any threshold content (irrespective of whether or not such content is adventitious or technically unavoidable). If co-existence measures were therefore to operate by reference to a baseline norm, there is a very real risk that the "organic" label could become defunct since it could not be attached to any agricultural product with a detectable GM content.

THE COMMISSION'S COEXISTENCE RECOMMENDATION

53. The intention of the Recommendation, which pre-dates the entry into force of Regulation 1829/2003 and 1830/2003, is to provide non-binding guidelines to Member States as to the principles they ought to apply in the development of national strategies on coexistence. Paragraph 1.5 of the Recommendation states:

"The present guidelines, which take the form of non-binding recommendations addressed to the Member States, should be seen in this context. Their scope extends from agricultural crop production on the farm up to the first point of sale, i.e. 'from the seed to the silo'.
The document is intended to help Member States develop national strategies and approaches to address coexistence. Focusing mainly on technical and procedural aspects, the guidelines provide a list of general principles and elements to aid Member States in establishing best practices for coexistence.
The document does not intend to provide a detailed set of measures that could be directly applied at Member State level. Many of the factors that are important in developing best practices for coexistence which are both efficient and cost-effective are specific to national and regional conditions.
Moreover, developing stewardship schemes and best practices for coexistence is a dynamic process that should leave room for improvement over time and take into account new developments based on scientific and technological progress".

54. As the Recommendation itself makes clear, therefore, it is not a binding instrument and the guidance it provides is just that and no more. Only Regulations, Directives and Decisions of the Community institutions are capable of having binding force and giving rise to enforceable obligations.

55. The Recommendation does, however, reflect the Commission's "thinking" on the purpose of coexistence measures and the relationship between coexistence and labelling. We consider that the guidelines betray a legislative interpretation that is fundamentally flawed in two important respects.

56. First, as recorded above, the Recommendation asserts that coexistence measures (or at least those envisaged in the Recommendation) are concerned solely with economic aspects since health and environmental issues are addressed by the GMO authorisation process. For the reasons we have set out above, that approach is incorrect.

57. Secondly, the Recommendation refers to a number of factors that Member States are advised to consider in developing their national strategies. One such factor is the labelling threshold; and the Recommendation provides:

"National strategies and best practices for coexistence should refer to the legal labelling thresholds and to applicable purity standards for GM food, feed and seed.

Presently, Council Regulation (EC) No 1139/98 (1), as last amended by Commission Regulation (EC) No 49/2000 (2), defines a labelling threshold for food of 1 %. Future labelling thresholds covering both food and feed are established in the Regulation on GM Food and Feed. These labelling thresholds would apply to conventional and organic farming alike. No legal thresholds exist for the adventitious presence of non-GMOs in GMOs. For seed of GM varieties, the general crop-specific requirements for purity standards in seed production apply.
The organic farming regulation (3) establishes that no GMOs shall be used in production. Thus, materials, including seeds, which are labelled as containing GMOs cannot be used. However, seed lots containing GM seeds below the seed thresholds (which would not need to be labelled for this GMO presence) could be used. The organic farming regulation does allow for the setting of a specific threshold for the unavoidable presence of GMOs, but no threshold has been set. In the absence of such a specific threshold, the general thresholds apply."

58. We are of the view that this paragraph indicates a flawed approach not only to labelling thresholds *per se* but also to the link between coexistence measures and those labelling thresholds. Furthermore, it betrays an interpretation of the Organic Regulation which we consider to be unsustainable.

59. It appears to gloss over the requirement that, in order to benefit from the labelling exemption, GM content must be adventitious or technically unavoidable, irrespective of the threshold. It would also appear to be suggesting that co-existence measures should relate to labelling thresholds as a baseline norm (which, for the reasons we have set out above, is a misinterpretation of the relevant legislation). It also assumes that organic products may contain GM product and yet remain "organic". Again, for the reasons set out above, we consider this to be wrong: the Organic Regulation does not afford or permit of any threshold content in products seeking an organic label.

60. For the sake of completeness, paragraph 2.1.4 of the Recommendation states that coexistence measures "shall not go beyond what is necessary in order to ensure that adventitious traces of GMOs stay below the tolerance thresholds set out in Community legislation". However, that cuts across the concept of coexistence employed in the Recommendation, which is that of the ability of farmers to make a "practical choice" between conventional, organic and GM crop production. The practicality of such a choice is affected by a range of factors such as technical

matters and consumer susceptibilities to which legislative tolerance thresholds are not necessarily relevant.

61. In conclusion therefore, we believe that the Recommendation is based on a fundamental misunderstanding of the relevant legal provisions and risks advising Member States to adopt coexistence measures that are incompatible with the aims of the legislation or which would result in preventing, in practice, the use of the "organic" label and the reliance on the GM labelling exemption.

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Gray's Inn,
London WC1R 5NR.

21 January 2005