

**IN THE MATTER OF DEFRA'S CONSULTATION
ON PROPOSALS FOR MANAGING THE COEXISTENCE OF GM,
CONVENTIONAL AND ORGANIC CROPS**

OPINION

INTRODUCTION

1. We are asked to advise Friends of the Earth, GM Freeze and the Soil Association on the current DEFRA Consultation on proposals for managing the coexistence of genetically modified ("GM"), conventional and organic crops commenced in July 2006 ("the Consultation"). We have previously advised on related issues arising from Directive 2001/18/EC (on the deliberate release into the environment of genetically modified organisms), 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) and will refer to that advice in the course of this Opinion. We are now asked to advise on whether or not the approach and assumptions of the Consultation are generally consistent with EC law and, specifically, in relation to the following:

- (i) Whether Article 22 of Directive 2001/18 changes the conclusions of our earlier advice;
- (ii) Whether the establishment of a 0.9% coexistence threshold for GM in non- GM crops is compatible with European law;
- (iii) Whether the exclusion of certain types of growing or farming activities *i.e.* private gardeners and allotment holders, farmers producing their own fodder and farmers who save seed for re-sowing for their next crop ("farm saved seed"), from the scope of the proposed measures is compatible with European law?
- (iv) Whether the position stated in the Consultation that Regulation 1829/2003 does not require the keeping of a public register of GM crop locations is compatible with Community law.

2. For the reasons set out below, the answer to each of those specific questions is "no".

3. The essential premise of the Consultation is that:

“...if authorised GM crops are grown here in due course this may result in non-GM crops having a small GM presence (e.g. through cross-pollination or the dispersal of GM seed). To facilitate choice between conventional, organic and GM crops, ‘coexistence’ measures will be needed to minimise unwanted mixing of GM and non-GM material. From a regulatory standpoint, the key benchmark for distinguishing GM and non-GM produce is the 0.9% threshold for adventitious GM presence adopted by the EU (products with a presence above this level must be labelled and sold as ‘GM’). In this paper Defra is seeking comments on a proposed coexistence regime for England that would aim to minimise any unwanted GM presence in non-GM crops so that it is below 0.9%.”

4. The Consultation further considers, *inter alia*, excluding from the scope of the co-existence measures crops that are not intended to be placed on the market, e.g. crops grown for private consumption.

5. We have considered the Consultation and have concluded, in summary, that:

- (i) It is based on a flawed approach to the link between co-existence measures and the GM labelling thresholds provided for in EC legislation and to the labelling thresholds *per se*.
- (ii) 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 is a misinterpretation of the relevant legislation).
- (iii) Further, 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 and wholly fails to grapple with the meaning of that term. We have concluded that a co-existence regime which aims to establish a base-line threshold of 0.9% GM content across the board would generally preclude any reliance in practice by operators on the labelling exemption for “adventitious” presence below that threshold if an element of GM content became inherent in all products. Furthermore, reliance by the operator on any base-line threshold resulting from co-existence measures would not in our view be sufficient to discharge

the burden placed upon him to demonstrate that the presence was “technically unavoidable”.

- (iv) Its position that there is no requirement in law for a public register is fundamentally flawed and ignores the provisions of Directive 2001/18.

6. Before discussing our conclusions, we consider it helpful to rehearse the legislative background applicable to the regulation of GM products.

LEGISLATIVE BACKGROUND

7. Directive 2001/18 (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 for the purpose of protecting human health and the environment when:

- carrying out the deliberate release into the environment of genetically modified organisms for any purposes other than placing on the market within the Community, and
- placing on the market genetically modified organisms as or in products within the Community¹.

8. 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 not be deliberately released or placed on the market unless that is in conformity with the Directive².

9. 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.

¹ Article 1

² Article 4

10. 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, a release may take place only with and subject to the conditions of an authorisation from the competent authority of a Member State. An authorisation has effect throughout the Community.
11. It follows therefore that Community law does not permit of any tolerance in relation to GMO content where the relevant GMO release has not been authorised. 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 met³.

LABELLING

12. 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 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

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

thresholds established under the provisions of Article 30(2), provided that these traces are adventitious or technically unavoidable.”

13. 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 Regulation 1830/2003.

14. Regulations 1829/2003 and 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 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 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.”

15. 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 1831/2003 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” (emphasis added)..

16. 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.”

17. Parallel provisions apply in relation to GM feed.

18. 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, who 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”.

19. For the sake of completeness, it should be noted that the provisions referred to above are concerned with identifying the circumstances in which something must be labelled as a GM product. If, for example, a product has an adventitious GM

content of less than 0.9%, that means that it is excluded from the obligation to be labelled as containing GMO. It does not follow that a positive representation can be made about the product (whether in the form of a label or some other statement about it) that it is GMO-free. Hence, the labelling requirements are not intended to lay down the borderline between GMO products and non-GMO products.

CO-EXISTENCE

20. 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” (emphasis added).

21. It is this provision which forms the basis of the UK government’s Consultation on co-existence, which appears to be firmly rooted in the Commission’s policy in that regard, as recorded in its 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”.

GENERAL CONCLUSIONS REGARDING THE CONSULTATION

22. Just as we considered in our previous advice that the Commission Recommendation had no basis in Community legislation and was wrong in law, we are of the view that certain assumptions and premises of DEFRA’s Consultation are also flawed and inconsistent with Community law.

23. The central premise of the Consultation is that coexistence measures are designed merely to minimise unwanted GM transfer and that such measures are to be defined by reference to the thresholds applicable to GM labelling requirements. Further, the Consultation is strongly reliant on the premise that coexistence measures are concerned only with “economic choice” and not with safety and environmental concerns. As we have already advised, that is a flawed approach to the Community legislation for a number of reasons.

COEXISTENCE AND BASELINE NORMS

24. 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.”

25. 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.

26. 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”.

27. 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.

28. The labelling thresholds are therefore legally irrelevant so far as the scope of coexistence 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, as the Consultation paper asserts (see, for example, at paragraphs 22 to 25).

29. 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, reliant on, or necessarily allied to 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.
30. 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”.
31. 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.
32. 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.
33. 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 baseline norm of 0.9% (rather than achieving lower levels of, or the avoidance

altogether of, contamination) arguably renders it more difficult in practice for non-GM operators to ensure that they benefit from the labelling exemption.

34. 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.

35. 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 (arbitrarily fixed) tolerance levels.

36. The Consultation also appears to indicate (see for example at paragraphs 28 and 36) that the construction of Article 26a is to be tempered by reference to the principle of proportionality and appears to suggest that, since it is unrealistic for producers to strive to avoid GM presence completely, the only appropriate response is to apply a baseline norm of 0.9%. In the same vein, the Commission has referred to Article 22 of the Directive as imposing – or at least implying - a similar constraint upon the extent of coexistence measures (Article 22 provides: “Without prejudice to Article 23, Member States may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive”).

37. We do not consider that either of those contentions has any bearing on the proper construction of the Community legislation. Nor do they provide justification for reliance on baseline norms founded upon the labelling requirements.

38. As regards the principle of proportionality, what is proportionate in the circumstances is a matter of fact and technical assessment and must have regard to the legislative aim. The analogy often used to illustrate the principle of proportionality is the wielding of a sledge hammer to crack a walnut. The objective is to crack open the walnut. By using a sledge hammer, the objective will be achieved. However, recourse to the sledge hammer involves the exercise of more force and energy than is necessary to achieve the objective. The objective could be achieved by using lesser force and energy (recourse to a

nutcracker). Thus, proportionality is concerned with ensuring that, of the different means *capable of achieving the legislative objective*, the one that is least burdensome (or, putting it another way, most efficient) is adopted.

39. In the present context, the legislative objective is avoiding, as opposed to minimising, the unintended presence of GM in other products. Proportionality will always be informed by what is technically possible in order to achieve the legislative objective; but there does not appear to be any evidential basis for an assertion that measures going beyond minimising contamination by reference to baseline norms founded upon the labelling provisions pose a disproportionate burden upon producers and operators having regard to the need to achieve the legislative objective. On the contrary, the problem posed by opting for a baseline norm is that it does not achieve the legislative objective at all. Reverting to the sledge hammer and walnut example, opting for a baseline norm on the ground of proportionality is like saying “we need to crack open this walnut; this rubber play-knife is lighter than this nutcracker and requires less force and energy; accordingly, proportionality requires use to apply the rubber knife to the walnut and throw the nutcracker away, even though this means that we will not be able to crack open the walnut”. It hardly needs stating that that is not a correct understanding of the principle of proportionality: that principle does not provide an excuse for failing to achieve the legislative objective.

40. Another problem about using a baseline norm derived from the labelling requirements is that it would seem to take the domestic measures outside the scope of Article 26a. Properly understood, a system based on the labelling requirements would amount to nothing more than a system designed to ensure that producers would not be obliged to label their products as containing GMOs (although we are sceptical as to the effectiveness of such a system). We do not think that coexistence can simply be assimilated to being relieved of the obligation to label one’s products as containing GMOs. It is rather more than that (whence the fact that Article 26a uses the verb “avoid”, not “minimise”).

41. Similarly, we do not consider that Article 22 of the Directive can be employed to distort the clear intention of Article 26a. Article 22 is directed toward ensuring that GMOs that benefit from a consent can be marketed without further restriction on the part of Member States, save where new safety and environmental concerns arise. Co-existence measures are directed towards avoiding cross contamination

to preserve the integrity of non-GM production, whilst accepting the legitimacy of GM production. Article 22 can have any relevance to coexistence measures only if, as a matter of fact, measures which aim to avoid cross contamination have the effect of preventing or unduly restricting the marketing of GM. There is simply no basis at all for the assertion that any particular measure designed to avoid cross contamination produces that result or, more importantly, that the only means of ensuring compliance with Article 22 is the establishment of a baseline norm for GM content.

42. In summary, therefore, we conclude that there is no legislative provision which requires a 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 or implying such a limitation. We consider therefore that the approach of the Consultation in promoting co-existence measures which seek to achieve a base-line norm by reference to the labelling requirements as fundamentally flawed. Moreover, we consider that such an approach has important consequences for operators seeking to benefit from the exemption to the labelling requirements, which is dependant on the meaning of the "adventitious or technically unavoidable" proviso in the relevant labelling provisions.

43. 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.

44. 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.

45. "Adventitious" is defined in the Oxford English Dictionary as:

"Coming from without, accidental, causal."

Our examination of other language versions of the term do not suggest that that is an unreliable guide to the meaning of the word. 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 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.”

46. 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.
47. 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.
48. 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.

49. 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 view be sufficient to discharge the burden placed upon him to demonstrate that the presence was “technically unavoidable”.

50. 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.

CO-EXISTENCE AND ECONOMIC CHOICE

51. We do not consider that the sole purpose of measures taken under Article 26a is to ensure economic choice for operators. It is significant that Article 26a was introduced into the Directive by Regulation No. 1829/2003, which 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.

52. 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 (Articles 1 and 4 of the Directive specifically require that the precautionary principle informs implementation of the Directive’s provisions).

53. 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 requirements⁴ and a safeguard clause to suspend and withdraw GM products⁵. 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, 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.”

54. 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.

EXCLUSION OF NON-COMMERCIAL PRODUCTION

55. The Consultation seeks to exclude from the scope of coexistence measures crops that are not intended to be placed on the market, such as allotment crops intended for private consumption on the basis that they are not subject to the labelling requirements.

56. Again, in our view, this approach is fundamentally flawed. For the reasons we have set out above, we do not consider that the labelling requirements have any legal relevance to co-existence measures. Co-existence measures are designed to avoid the unintended presence of GM “in other products”. Article 26a of the Directive is not confined to products intended to be marketed. Even if it were however, it would not absolve Member States of the responsibility of seeking to avoid cross contamination of commercial crops via non-commercial crops. We do not therefore consider it permissible to exclude non-commercial crops from the scope of coexistence measures on the basis that they are not subject to the labelling requirements.

57. Furthermore the legislative reach of Directive 2001/18 and Regulation 1829/2003 is not confined to commercially exploited products. Both the Directive and the Regulation regulate the placing on the market of GMOs and include in the definition of “placing on the market” the making available of products to third parties free of charge.

A PUBLIC REGISTER

58. The Consultation discusses the pros and cons of establishing and maintaining a public register of GM sites on the basis that DEFRA has discretion in the matter. The Consultation states expressly that Regulation 1829/2003 does not require any such register.

59. There is no question but that this premise is wholly incorrect. Article 31(3) of Directive 2001/18 which falls under Part D of the Directive provides:

“Without prejudice to paragraph 2 and point A.7 of Annex IV,

(a) Member States shall establish public registers in which the location of the release of the GMOs under Part B is recorded.

(b) Member States shall also establish registers for recording the location of GMOs grown under Part C, *inter alia* so that the possible effects of such GMOs on the environment may be monitored in accordance with the provisions of Articles 19(3)(f) and 20(1). Without prejudice to such provisions in Articles 19 and 20, the said locations shall

- be notified to the competent authorities and

- be made known to the public

in the manner deemed appropriate by the competent authorities and in accordance with national provisions.

60. Articles 7 and 19 of Regulation 1829/2003 deal with authorisations under that Regulation. Articles 7(8) and 19(8) provide:

References made in parts A and D of Directive 2001/18/EC to GMOs authorised under part C of that Directive shall be considered as applying equally to GMOs authorised under this Regulation.

61. We consider that the reference in Article 31(3) of the Directive to GMOs “grown” under Part C necessarily refers to GMOs authorised under Part C. Articles 7(8) and 19(8) of the Regulation therefore apply the provisions of Part D of the Directive (which includes Article 31) to GM food and feed authorised under the Regulation. It is beyond serious argument therefore that there is a requirement for a public register of all GM crop locations. Since the purpose of the register is to enable monitoring of the effects of GMOs on the environment, it is clear that any obligation to be register must arise as soon as the crop is planted in that location.

KPE LASOK QC
REBECCA HAYNES
13th October 2006