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New regulation for labeling genetically modified foods: A solution or a problem?

To the editor:

On May 26, 1998, the European Union approved regulation CE 1139/98, concerning the different presentation of information on food labels compared to that originally considered in regulation CE 258/97 (*Nat. Biotechnol.* 16:605, July 1998).

The earlier directive (CE 258/97) states that labeling must applied to novel foods and their ingredients produced by means of genetic engineering (1) when there is no substantial equivalence between a novel food and its original counterpart; (2) when materials present in the novel food are not present in an equivalent non-modified product and may have consequences for the health of certain groups of people; (3) when the novel food contains biotechnologically derived material that may present ethical problems; and (4) when living genetically modified organisms (GMOs) are present in the novel food.

In contrast, the latest regulation (CE 1139/98) establishes a requirement to label all foods and food ingredients made either wholly or partly from seeds derived from genetically modified soya or maize (specifically considered in directives 97/281/CE and 97/98) whenever DNA or protein derived from genetic modification is detected in the food. Labeling, as defined in the most recent regulation, will become compulsory in September. While the consumer has the right to be kept informed, we believe that the new regulation will be a source of confusion.

Two important legal problems are evident since the approval of CE 1139/98. First, the earlier regulation applied to all novel foods and only required the labeling of those that did not comply with the four points listed above, independently of the presence of transgenic genes or proteins. However, CE 1139/98 establishes the presence of transgenic genes or proteins as the only factor in determining the necessity for labeling two specific transgenic products and their derivatives (i.e., soya and maize). A special regulation for only two specific cases is contradictory with the general rules previously established.

Second, and more important, the new regulation requires the availability of a technique that can guarantee the detection of transgenic DNA and protein. However, the detection of "transgenic" DNA or protein is not an easy task, and currently there is no officially validated protocol available for use. As highlighted in one of the considerations of CE 1139/98, it is necessary to develop common, scientifically approved methods of detection.

Currently, a few private companies and public laboratories are offering a PCR-based method for the detection of traces of specific transgenic genes in soya and maize. While there is a European Community project (SMT4-CT96-2072) aimed at the development of analytical methods, no such method is currently validated.

Bearing in mind the potential sensitivity of PCR-based techniques, it would also be necessary to establish threshold levels above which labeling should be mandatory. In fact, CE 1139/98 notes in one of its considerations that the necessity to label accidentally contaminated material could be avoided by establishing thresholds.

However, these levels have not been defined. There is, therefore, a basic lack of technical knowledge which, in our opinion, will make it very difficult to apply the new regulation. It will be interesting to observe the legal consequences of the harmonization between the two regulations in the coming months. In the event of the commercialization of new genetically modified foods, will new rules appear for each one, or will regulation CE 258/97 be sufficient?

We consider that regulation CE1139/98 was produced in too much haste. To discuss the detection of transgenic DNA and protein when the methods to do so are not yet developed will only serve to confuse the consumer. One of the possible consequences (and an argument that could be used by groups against the commercialization of genetically modified foods) may be the loss of confidence in scientists who, while being able to introduce genetic modifications, are unable to detect them. The pressure exerted during the last few months by different groups is without doubt the unfortunate explanation of this haste.

The reaction of scientists should not be to wait: On the one hand, scientists actively working in food biotechnology should leave the relative isolation of their labs and inform the general population following the example of the referendum in Switzerland, and on the other, those working in the area of detection should redouble their efforts in validating suitable techniques as soon as possible and make them available to the consumer. Only in this way will credibility and trust be won in food biotechnology.

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Skewing the numbers

To the editor:

Regarding your feature article, "Public biotech: The numbers" (*Nat. Biotechnol.* 16:425–427, May 1998), I was surprised to find Quintiles Transnational listed among the 380 public biotechnology companies. Quintiles is mainly a contract research organization, and with its quite sizable revenue (about US$815 million, or 5% of the industry revenues), inclusion of a primarily service company into your calculations introduces a serious bias in the author's analysis.

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