



S H E E T

## ***General Biotechnology Information and Labeling Guidance***

Genetically modified organisms (GMOs) are defined as plants or other organisms in which the genetic material of the organism has been altered in a way that does not occur naturally by mating or natural recombination. Biotechnology, bioengineering, genetic engineering, genetically modified (GM) are all terms that are generally used to describe the technology by which plants or other organisms are developed using recombinant deoxyribonucleic acid (rDNA) technology. This technology allows selected individual genes to be transferred from one organism to another including between non-related species.

### United States

In the United States, there are not specific regulations requiring special labeling for foods or food additives derived from biotechnology and labeling of these materials is generally voluntary unless the bioengineered food or food additive no longer can be adequately described commonly or nutritionally by the name used for the traditional counterpart or the bioengineered food contains an allergen that would not be expected by the nature of the traditional counterpart food.

With regard to voluntary labeling of foods derived from biotechnology, in 2001 the FDA issued a Draft Guidance for Industry on the subject<sup>1</sup>. Some manufacturers may choose to indicate on their labels the presence or absence of foods or food additives derived from biotechnology. In doing so, the statements used to describe the ingredients must be truthful and not misleading. Towards this goal, the FDA has included in the Guidance information on how certain terms should be used. Use of the statement “not genetically modified” without referring to the use of biotechnology is misleading in that genetic modification can refer to traditional alterations of plant genotypes that do not necessarily fall into the category of bioengineering.

The term “GMO free” is also misleading. Most foods, other than yogurt and seeds, do not contain organisms. Further, the term “free” indicates a claim that absolutely no bioengineered material is present which, due to the possibility of an adventitious presence of bioengineered material, could not be substantiated using currently available testing methods. Further, the prevalent perception of consumers participating in FDA Focus Groups on Biotechnology<sup>2</sup> was that “free” means zero. The guidance suggests that the accuracy of the term “free” can only be ensured once it has been defined or a threshold level for bioengineered material that can be tested against is established. FDA has not indicated the intent to define the term “free” of bioengineered material or set a threshold level. More appropriate terminology for indicating the absence of

bioengineered materials is provided in the Guidance. For example, the following statement could be used without being misleading “We do not use ingredients that were produced using biotechnology.”

Manufacturers that wish to make claims about the absence of bioengineered ingredients must be able to substantiate the claim. Substantiation methods indicated in FDA’s Guidance include testing and documented handling practices and procedures.

## European Union

In the EU, the treatment of labeling of foods and food additives derived from biotechnology is treated somewhat differently. Currently, the Novel Foods Regulation<sup>3</sup> requires mandatory labeling of foods and food ingredients derived from biotechnology. However, products initially derived from biotechnology that no longer contain protein or DNA resulting from genetic modification are exempt from these labeling requirements as long as the bioengineered food is not substantially different by characteristic or property from the traditional food<sup>4</sup>. See the chart<sup>5</sup> provided below for specific examples of products that would be exempt from biotechnology labeling under current regulations. Additionally, for traditionally produced products, where biotechnologies do exist within the product group, a threshold for adventitious contamination by bioengineered materials has been established by Regulation (EC) 49/2000<sup>6</sup> at 1% under which products do not require biotechnology labeling. This threshold applies to adventitious contamination only and manufacturers must be able to demonstrate that they have used appropriate steps to avoid the presence of material derived from biotechnology to be exempt from labeling requirements.

In July, 2001, the European Commission adopted two proposals affecting the traceability and labeling of foods and food ingredients and feeds produced using biotechnology<sup>7</sup>. These proposals including amendments were affirmed by the European Parliament in July, 2002 and are predicted to be approved by the Council later in 2002. The proposals define a model for labeling biotechnology products that is more comprehensive than the current legislation. Under the proposals, all foods or food ingredients derived from biotechnology, regardless of the protein/DNA content of the final product (see chart<sup>5</sup> below for examples), would be required to bear special labeling indicating such derivation. Note that food additives such as highly filtered lecithin derived or potentially derived from plants produced through biotechnology will need to be labeled under the new labeling proposals even if they do not contain any detectable protein or DNA content. Additionally, the threshold for adventitious contamination would be lowered to 0.5%.

There has been much debate in the EU regarding the appropriateness and feasibility of these proposals. In the Working Document of the Commission Services on Traceability and Labelling of GMO’s and Products Derived From GMO’s<sup>8</sup> (ENV/620/2000) several options for the labeling of products derived from biotechnology were suggested, one of which was the basis for the 2001 European Commission proposals which were recently affirmed by the European Parliament.

However, there has been support for another option presented in the Working Document which, maintains current labeling requirements and adds a “GMO-free” scheme. This scheme would provide a voluntary program that would detail a comprehensive system for a method of producing products without the use of biotechnology which would allow manufacturers to make a “GMO-free” claim that is not misleading and truthful. Additionally, there has been discussion regarding the availability and capability of analytical tests to detect adventitious contamination at the proposed 0.5% level. At this time it is unclear what the final regulation will require or provide for.

Colorcon intends to continue to monitor the regulatory situation with regard to the use of biotechnology and will update this information sheet as appropriate.

## **References**

<sup>1</sup>U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering  
<http://www.cfsan.fda.gov/~dms/biolabgu.html>

<sup>2</sup>U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Report on Consumer Focus Groups on Biotechnology  
<http://www.cfsan.fda.gov/~comm/biorpt.html>

<sup>3</sup>Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 Concerning Novel Foods and Novel Food Ingredients  
[http://europa.eu.int/smartapi/cgi/sga\\_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=31997R0258&model=guichett](http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=31997R0258&model=guichett)

<sup>4</sup>Council Regulation (EC) No 1139/98 of 26 May 1998 Concerning the Compulsory Indication of the Labelling of Certain Foodstuffs Produced From Genetically Modified Organisms of Particulars Other Than Those Provided for in Directive 79/112/EEC  
[http://europa.eu.int/comm/food/fs/gmo/legal\\_oj/reg1139-98\\_en.pdf](http://europa.eu.int/comm/food/fs/gmo/legal_oj/reg1139-98_en.pdf)

<sup>5</sup>Chart-Excerpt from EUROPA-European Union On-line's Question and Answers on the regulation of GMOs in the EU

[http://europa.eu.int/rapid/start/cgi/guesten.ksh?p\\_action.gettxt=gt&doc=MEMO/02/160|0|RAPID&lg=EN&display=](http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=MEMO/02/160|0|RAPID&lg=EN&display=)

**Labelling of GM-Food and GM-Feed Examples <sup>(16)</sup>**

<b>GMO-type</b>	<b>EXAMPLE</b>	<b>Labelling Required at present</b>	<b>Labelling required in future</b>
GM plant	Chicory <sup>(17)</sup>	Yes	Yes
GM seed	Maize seeds	Yes	Yes
GM food	Maize, Soybean sprouts, Tomato	Yes	Yes
Food produced from GMOs	Maize flour <sup>(18)</sup>	Yes	Yes
	Highly refined maize oil, soybean oil, rape seed oil <sup>(19)</sup>	No	Yes
	Glucose syrup produced from maize starch \* MERGEFORMAT 17	No	Yes
Food from animals fed on GM feed	Eggs, meat, milk	No	No
Food produced with the help of a GM enzyme	bakery products produced with the help of amylase	No	No
Food additive/flavouring produced from GMOs	Highly filtered lecithin extracted from GM soybeans used in chocolate \* MERGEFORMAT 17	No	Yes
GM Feed	Maize <sup>(20)</sup>	Yes	Yes
Feed produced from a GMO	Corn gluten feed, Soybean meal	No	Yes
Feed additive produced from a GMO	Vitamin B2 (riboflavin)	No	Yes

<sup>(16)</sup> The examples include foods which have not been authorised for marketing in the EU. See Annex II for a list of products which can legally be marketed in the EU.

<sup>(17)</sup> One chicory has been approved for breeding purposes under Directive 90/220/EC, but not for food use

<sup>(18)</sup> DNA or protein of GM origin detectable in the final product.

<sup>(19)</sup> DNA or protein of GM origin not detectable in the final product.

<sup>(20)</sup> The current labelling rules entered into force in 1997, and do not include four GMOs approved prior to that date.

<sup>6</sup>Commision Regulation (EC) No. 49/2000 of 10 January 2000 Amending Council Regulation (EC) No. 1139/98 Concerning the Compulsory Indication on the Labelling of Certain Foodstuffs Produced From Genetically Modified Organisms of Particulars

Other Than Those Provided for in Directive 79/112/EEC  
[http://europa.eu.int/comm/food/fs/gmo/legal\\_oj/reg49-2000\\_en.pdf](http://europa.eu.int/comm/food/fs/gmo/legal_oj/reg49-2000_en.pdf)

<sup>7</sup>Regulation of the European Parliament and of the Council Concerning 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 [http://europa.eu.int/comm/food/fs/gmo/biotech09\\_en.pdf](http://europa.eu.int/comm/food/fs/gmo/biotech09_en.pdf) Regulation of the European Parliament and of the Council on Genetically Modified Food and Feed [http://europa.eu.int/comm/food/fs/gmo/biotech08\\_en.pdf](http://europa.eu.int/comm/food/fs/gmo/biotech08_en.pdf)

<sup>8</sup>Working Document of the Commission Services on Traceability and Labelling of GMOs and Products Derived From GMOs  
[http://europa.eu.int/comm/food/fs/gmo/biotech01\\_en.pdf](http://europa.eu.int/comm/food/fs/gmo/biotech01_en.pdf)

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### World Headquarters

Colorcon

415 Moyer Blvd., P.O. Box 24, West Point, PA 19486-0024

Tel: 215-699-7733 Fax: 215-661-2605 Website: [www.colorcon.com/pharma](http://www.colorcon.com/pharma)

e-mail: [info@colorcon.com](mailto:info@colorcon.com)

Locations	Telephone	Facsimile	Locations	Telephone	Facsimile
<i>United States</i>			<i>Asia/Pacific</i>		
Santa Ana, California	714-549-0631	714-549-4921	Singapore	65-6438-0318	65-6438-0178
Indianapolis, Indiana	317-545-6211	317-545-6218	Fuji-gun, Shizuoka, Japan	81-5-4465-2711	81-5-4465-2730
Humacao, Puerto Rico	787-852-3815	787-852-0030	Shanghai, China	86-21-5442-2222	86-21-5442-2229
Stoughton, Wisconsin	608-887-8970	608-887-8984	Goa, India	91-832-288-3434	91-832-288-3440
			Gyeonggi-do, Korea	82-31-296-2173	82-31-296-2178
<i>Canada</i>					
St. Laurent, QC, Canada	514-337-8341	514-337-9159			
<i>Europe</i>			<i>Latin America</i>		
Dartford, Kent, England	44-1322-293000	44-1322-627200	Buenos Aires, Argentina	54-11-4552-1565	54-11-4552-3997
Massey, France	33-1-6447-9750	33-1-6932-5983	Cotia, Brasil	55-11-4612-4262	55-11-4612-3307
Idstein, Germany	49-6126-9961-0	49-6126-9961-11	Bogota, Colombia	571-418-1202	571-418-1257
Gallarate, Italy	39-0331-776932	39-0331-776831	Caracas, Venezuela	58-212-237-9842	58-212-238-2259
Budapest, Hungary	36-1-200-8000	36-1-200-8010	Santa Fe, México	52-55-3000-5700	52-55-3000-5701 /02
Istanbul, Turkey	90-216-465-0360	90-216-465-0361			
Barcelona, Spain	34-9-3589-3756	34-9-3589-3792			

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