USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Voluntary _ Public

Date: 7/14/2014
GAIN Report Number: E14034

EU-28

Post: Brussels USEU

Negative List for Novel Foods and Ingredients

Report Categories:
Exporter Guide

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Report Highlights:
The current Novel Foods Regulation 258/97 requires that all food and food ingredients that have not been used for human consumption in the EU before May 15, 1997 be considered a novel food or a novel food ingredient. The broad scope of what is currently considered a novel food presents challenges for U.S. exporters in determining the legal status of specific substances or ingredients. This report provides an overview of the current novel foods regulatory environment and uses RASFF alerts to construct a negative list of substances and ingredients not authorized under the current novel foods framework.

Introduction:

The current Novel Foods Regulation 258/97 requires that all food and food ingredients that have not been used for human consumption in the EU before May 15, 1997 be considered a novel food or a novel food ingredient. All novel foods must be authorized before being sold on the European market. Unlike food additives (Regulation 1333/2008) and food supplements (Directive 2002/46), a positive list of novel foods and ingredients does not yet exist. The broad scope of what is currently considered a novel food presents challenges for U.S. exporters in determining the legal status of specific substances or ingredients. Since 2009, the EU Rapid Alert System for Food and Feed (RASFF) has issued152 notifications and alerts directly related to unauthorized novel foods or novel ingredients in the European market with 65 of them directed at products of U.S. origin. This report provides an overview of the current novel foods regulatory environment and uses RASFF alerts to construct a negative list of substances and ingredients not authorized under the current novel foods framework.

Positive and Negative Lists for Other Product Categories

The EU has a tradition of providing positive lists of substances and ingredients in other regulatory frameworks to provide guidance to food business operators. If a substance is not included on the positive list, it may not be marketed in the EU. Under the food additives framework legislation 1333/2008, the EU provides a positive database of approved food additives along with the maximum levels that can be used with no adverse effect for human consumption.

Food supplements Directive 2002/46/EC also provides a positive list of permitted vitamin and mineral preparations that can be added for specific nutritional purposes in food supplements. This list has been regularly updated (Directive 2006/37/EC, Regulation 1170/2009, Regulation 1161/2011, Regulation 119/2014) with the understanding that products not included in this list have been prohibited since August 1, 2005. This list does not set EU harmonized maximum or minimum levels, leaving them to individual Member State legislation. Additionally, botanical supplements are not regulated under this directive and are instead regulated at the Member State level.

Existence of the Novel Foods Catalogue

The EU provides guidance on novel foods and ingredients through the Novel Foods Catalogue maintained by DG Health and Consumers. It is important to note that the catalogue is non-exhaustive and serves for informational purposes only. Unlike the positive lists for food additives and supplements, the Novel Food Catalogue has no legal value for producers and importers seeking to market the substances and ingredients included in the catalogue. Another restriction on the use of the catalogue is that under the novel foods framework, some Member States may further restrict the marketing of a novel food through specific legislation. Thus a U.S. exporter would have a very difficult time determining which novel foods or substances are authorized.

Current Authorization Procedure

To obtain authorization to market a novel food or novel ingredient in the EU, an organization must make an application to a Member State. After receiving an application, the competent authority will issue a safety assessment report on the novel food indicating any risks for human health. The competent authority then forwards this assessment to all Member States for additional comments. If there are no objections, an authorization can be granted and the novel food can immediately be marketed in the EU.

If one or more Member States object to the assessment of the product, the European Commission will ask the European Food Safety Authority (EFSA) to carry out an assessment of the novel food and publish the acceptance or rejection of the product in the Official Journal of the European Union. The Commission website only lists the authorizations and rejections published in the Official Journal.

This system is problematic for U.S. exporters because authorizations that face no negative feedback from the Member States are not published in the Official Journal, thus preventing the creation of a definitive positive list of novel foods.

Exceptions to the Authorization Procedure

Novel foods authorizations are not automatically granted to foods and ingredients already authorized under other legislation. Other important regulatory frameworks include food additives, flavorings for use in foods, extraction solvents used in food production, and genetically-modified organisms (GMO) for food and feed. Additionally, products formerly authorized as food supplements that have new uses in other foods require new authorization under the novel foods regulation.

For example, an authorization under the food additives legislation for steviol glycosides extracted from the leaves of the *Stevia rebaudiana* plant does not automatically result in an authorization under the novel foods regulation. In this case, an authorization is still pending at the Member State level to authorize *Stevia rebaudiana* leaves as a novel food. U.S. exporters must take special note of how a novel food is being used before determining the regulatory framework that governs the product.

RASFF Notifications and a Negative List

RASFF alerts and notifications allow for comprehensive management of food safety issues throughout the EU. RASFF notifications are publicly available and sent whenever a food safety threat is identified, predominately when products are inspected at the border. Through these detailed reports, FAS is able to track the product characteristics that initiate the notification, including improper paperwork, unauthorized ingredients, GMO content, etc., among other hazards.

We draw on RASFF reports that identify the presence of unauthorized novel foods as a source

to generate a negative list of novel foods for U.S. exporters, which is presented in Appendix I. This list includes all RASFF alerts since 2009 concerning U.S. shipments of novel foods. Also included is the most recent information concerning the authorization of the novel food or ingredient.

In addition to a negative list, Appendix II presents the list of novel food ingredients that have resulted in RASFF alerts for all shipments by region. While many of these novel foods appear to be regionally-specific, they may provide additional guidance to U.S. exporters. It is worth noting that producers operating inside of the EU face a similar incidence of regulatory enforcement in the marketing of novel foods as U.S. exporters.

Moving Forward

In December 2013, the European Commission presented a new proposal for a revision of the current Novel Foods Regulation 258/97. This proposal involves the creation of an EU centralized authorization procedure for novel foods as well as the generation of an updated catalogue and positive list of novel foods. This proposal must now be put before the European Parliament. For more information on the novel foods proposal, refer to GAIN Report: Proposal for a New Novel Foods Framework Regulation.

Appendix I: Negative List of Novel Food Ingredients

As this list comprises RASFF notifications from 2009 to present, it is possible that many of the novel foods or novel ingredients facing regulatory barriers are in the process of authorization. Below is a list of all ingredients or products contained in U.S. imports triggering RASFF notifications. For some products, links to the latest updates concerning each item are included. Where possible, the link to the product information contained in the Novel Foods Catalogue is provided. As explained above, the Novel Foods Catalogue is for informational purposes only and should not be referenced as a legal document.

Novel Food/Ingredient	**Common Names**	**Current Status**
Betaine		Not authorized as a novel food. EFSA found insufficient evidence to support the application of betaine as a novel food in the EU.
Butea superba		Not authorized as a novel food.
Citrulline		Not authorized as a novel food. EFSA has additionally rejected health claims associated with this ingredient.
Clinoptilolite		Not authorized as a novel food. The UK competent authority rejected the application for the volcanic sand in 2005. Also known as zeolite.
Cnidium monnieri	Cnidium fruit, Herbal viagra	Not authorized as a novel food.

Coriolus versicolor	Turkey Tail	Not authorized as a novel food. Also applies to *Trametes versicolor*.
Creatine Monohydrate		Not authorized. For EU references on the use of creatine supplementation for nutritional purposes refer to the Annex Foods for Sport People. This may also cover other creatine derivatives such as *tri creatine malate* and *tri creatine orotate*.
Epimedium grandiflorum	Large flowered barrenwort, Bishop's hat	Not authorized as a novel food.
Eurycoma longifolia	Tongkat Ali	Not authorized as a novel food.
GTF chromium yeast		Not authorized as a novel food or as a supplement.
Gynostemma pentaphyllum	Jiaogulan	Not authorized as a novel food.
Hoodia gordonii	Hoodia cactus, Hoodia	Not authorized as a novel food.
Huperzia serrata		Not authorized as a novel food in the EU. The request concerns extracts from the whole plant.
Indole 3 carbinol (in pure form)		Not authorized as a novel food.
Inonotus obliquus	Cinder conk, Chaga	Not authorized as a novel food. The use of the mushroom is permitted in food supplements.
Irvingia gabonensis	African mango, Wild mango, African green mango, Dika, Ogbono, Bush mango	The fruit, fruit extracts, and any non-aqueous seed extracts are considered novel foods and are not authorized according to the UK novel foods authority. The seeds of *Irvingia gabonensis*, commonly referred to as Ogbono seeds, are not considered novel foods.
Myrciaria dubi	Camu-camu	This product is only authorized as a food supplement in the EU. Any other uses are not currently authorized as a novel food.
Morinda citrifolia	Noni, Great morinda, Indian mulberry,Beach mulberry, Cheese fruit	Authorized as a novel food. Includes juice, leaves, puree, and concentrate.
Phellinus linteus	Black hoof mushroom	Not authorized as a novel food.
Piper methysticum	Kava, Kava-kava	Not authorized as a novel food.
Pueraria mirifica	Kwao Krua	Not authorized as a novel food.
Rhodiola rosea	Golden root, Rose root, Aaron's rod,Arctic root, King's crown,*O*rpin rose	Not authorized as a novel food and certain health claims denied.
Scutellaria elliptica	Hairy skullcap	Not authorized as a novel food.
Silybum marianum	Milk thistle, Marian	Not authorized as a novel food.

	Thistle, Variegated thistle, Scotch thistle	
Siraitia Grosvenorii	Buddha´s fruit	Not authorized as a novel food in the EU.
Stevia Rebaudiana	Stevia, Sweet leaf, Sugarleaf	Currently the plants and dried leaves of the *Stevia rebaudiana* Bertoni are not approved as a novel food according to Novel Foods Regulation 258/97. An application from EUSTAS (European Stevia Association) seeking approval for *Stevia rebaudiana* as a novel food was received by German competent authority for novel foods on 10 August 2007 where it has since been placed on hold. Steviol glycosides, an extract from the leaves of the *Stevia rebaudiana* Bertoni plant, have been approved for use as a sweetener (food additive E 960) under the food additives framework Regulation 1333/2008 on steviol glycosides.
Synsepalum dulcificum	Miracle fruit, Miracle berry plant	Not authorized as a novel food.

Appendix II: Novel Food Rejections by Region of Origin

The following table provides a list of all RASFF reported novel food rejections sorted by region from 2009 to present.

Africa	Asia	Europe	Oceania	South America	United States
Vernonia amygdalina	3,3 diindolylmethane (DIM)	Achyrantes bidentata Bl	Bee venom	Mesquite meal/powder	Betaine
Xilopia aethiopica	Aqua armeniacae	Asplenium scolopendrium L.		organic yacon root	Butea superba
	Betel nuts	Atractylodes macrocephala		Salvia hispanica	Citrulline
	Bombyx mori	Cistanche		Smallanthus sonchifolius	Clinoptilolite
	Bulbus fritillariae cirrhosae	Cistus incanus		Stevia rebaudiana	Cnidium monnieri
	Desmodium gangeticum	Clinoptilolite			Coriolus versicolor
	Dongling tea	Cnidium monnieri			Coriolus versicolor
	Epimedium	Coriolus			Creatine

	grandiflorum	versicolor			derivative
	Eurycoma longifolia	Creatine derivative			Creatine monohydrate
	Eurycoma longifolia	Cuscuta japonica			Epimedium grandiflorum
	Flos farfarae	D-ribose			Eurycoma longifolia
	Folium eriobotryae	Epimedium grandiflorum			GTF chromium yeast
	Ginseng	Esterified CLA (conjugated linoleic acid)			Gynostemma pentaphyllum
	Globe amaranth	Eurycoma longifolia			Hoodia gordonii
	Hoodia gordonii	Glechoma hederacea			Huperzia serrata
	Jiaogulan tea	Herba cistanches			Indole-3-carbinol (in pure form)
	Mucuna pruriens	Hoodia gordonii			Inonotus obliquus
	Peltranda virgilica	Irvingia gabonensis			Irvingia gabonensis
	Phyllanthus emblica (50 %)	Myrciaria dubia			Myrciaria dubia
	Pueraria mirifica	Radix paeonia alba			Noni
	Radix adenophorae	Rosa laevigata			Phellinus linteus
	Radix platycodonis	Rubus suavissimus			Pueraria mirifica
	Radix polygalae	Salvia hispanica			Rhodiola rosea
	Rhizoma pinelliae preparatum	Semen biotae			Scutellaria elliptica
	Siraitia grosvenorii	Siraitia Grosvenorii			Silybum marianum
	Stevia rebaudiana	Smallanthus sonchifolius			Siraitia grosvenorii
	Synsepalum dulcificum	Stevia rebaudiana			Stevia rebaudiana
	Terminalia chebula (45 %)				Synsepalum dulcificum
	Trametes versicolor				