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April 2019

## MARKET NEWS



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## About Sino Silliker

### Officially launch of Sino Silliker New COA

Sino Silliker 4 labs in Shanghai, Beijing, Qingdao, Ningbo have officially launch the new COA in Apr. 2019 due to LIMS upgrade. New COA has the following revisions:

1.New COA coding changes from No.LR\*\*\*\*\* to No.\*\*\*\*\* (\*represents numbers), the bar code place is changed as well.

**OLD EDITION**

中国认可  
国际互认  
检测  
TESTING  
CNAS L1512

SINO SILLIKER TESTING SERVICES (QINGDAO) CO., LTD.  
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**MERIEUX**  
NutriSciences

**Certificate of Analysis 分析证书** No.LR471592

**NEW EDITION**

MA 171500344191

中国认可  
国际互认  
检测  
TESTING  
CNAS L1512

Sino Silliker Testing Services (Qingdao) Co., Ltd.  
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**MERIEUX**  
NutriSciences

**Certificate of Analysis 分析证书**  
No.123456

2.In new COA, the information provided by clients such as company name, address, sample description etc. are shown in Italics.

To 致 *Foods Ltd. 食品有限公司*  
Address 地址 *中国山东青岛*  
Date of Report 报告日期 (yyyy/mm/dd): 2019/01/07

**NEW EDITION**

**Sample Information 样品信息**  
The following samples were supplied by/on behalf of the client 下列样品是客户或以客户的名义提供的:  
Date of Receipt 接样日期 (yyyy/mm/dd): 2018/09/30

Sample Description 样品描述	Condition on Receipt 接收时状态	Sample ID 样品编号
<i>样品描述 样品批号</i>	Solid/固体, Fresh/新鲜, 无包装/None, By express/快递	[2]
<i>样品描述2 样品批号2</i>	Solid/固体, Fresh/新鲜, 无包装/None, By express/快递	
<i>ceshi ceshi</i>	无包装/None, By express/快递	

Results apply only to the samples as received. The information in italics are supplied by the client and the client takes responsibility for their authenticity. Results are only for internal use by the client and not for public display as proof. Without the written permission of the company, any party is prohibited from using the test results and the official CoA for undue publicity.  
本结果仅适用于到样。以斜体字显示的信息由客户提供，其真实性由客户负责。本结果仅供客户内部使用，不作为具有证明作用的数据对外公开。未经我公司书面批准，不得擅自使用检验结果及证书进行不当宣传。

3.If determination of the third sampling limit of microorganisms is included in the new COA, the original 5 results determination will be combined into one integrated result determination.

S MC	Aerobic plate count 菌落总数 (CFU/mL)★2	GB 4789.2-2016	---	<1	n=5,c=2,m=1 00,M=10000	Pass 符合
S MC	Aerobic plate count 菌落总数 (CFU/mL)★2	GB 4789.2-2016	---	<1	n=5,c=2,m=1 00,M=10000	Pass 符合
S MC	Aerobic plate count 菌落总数 (CFU/mL)★2	GB 4789.2-2016	OLD EDITION	<1	n=5,c=2,m=1 00,M=10000	Pass 符合
S MC	Aerobic plate count 菌落总数 (CFU/mL)★2	GB 4789.2-2016	---	<1	n=5,c=2,m=1 00,M=10000	Pass 符合
S MC	Aerobic plate count 菌落总数 (CFU/mL)★2	GB 4789.2-2016	---	<1	n=5,c=2,m=1 00,M=10000	Pass 符合



Q MC	Aerobic plate count 菌落总数 (CFU/g)	FDA-BAM-Chapter 3:2001	---	1.24×10 <sup>2</sup>	<b>NEW EDITION</b>  n=5,c=2,m=10000,M=100000 【表中所示数据仅为测试使用】	Fail 不符合
Q MC	Aerobic plate count 菌落总数 (CFU/g)	FDA-BAM-Chapter 3:2001	---	2×10 <sup>4</sup>		
Q MC	Aerobic plate count 菌落总数 (CFU/g)	FDA-BAM-Chapter 3:2001	---	2×10 <sup>4</sup>		
Q MC	Aerobic plate count 菌落总数 (CFU/g)	FDA-BAM-Chapter 3:2001	---	1.24×10 <sup>2</sup>		
Q MC	Aerobic plate count 菌落总数 (CFU/g)	FDA-BAM-Chapter 3:2001	---	2.3451×10 <sup>4</sup>		

4.If the new COA includes pesticide residue package, the list of package will be shown separately from other results, it will be individually listed and positive result will be shown on top and non-detective items will be shown after.

Pesticide List 农残列表				
Start Test Date 检测开始日期: 2019/04/01 End Test Date 检测结束日期: 2019/04/03				
Sections 部门	Analytes (Units) 分析物 (单位)	Methods 方法	Rpt Lmt 报告限	Results 结果
Sample ID 样品编号: LR				
Multi-Pesticide Suite 190+ items 多种农残扫描190+项		<b>NEW EDITION</b>		
Q LC	097 Imidacloprid 吡虫啉 (mg/kg)	EN 15662:2018	0.01	0.11
Q GC	001 2-phenyl-phenol 邻苯基苯酚 (mg/kg)	EN 15662:2018	0.01	<0.01
Q LC	002 Acephate 乙酰甲胺磷 (mg/kg)	EN 15662:2018	0.01	<0.01
Q LC	003 Acetamiprid 啉虫脒 (mg/kg)	EN 15662:2018	0.01	<0.01
Q GC	004 Acetochlor 乙草胺 (mg/kg)	EN 15662:2018	0.01	<0.01
Q LC	005 Aldicarb 涕灭威 (mg/kg)	EN 15662:2018	0.01	<0.01
Q LC	006 Aldicarb-sulfone/Aldoxycarb 涕灭威威 (mg/kg) *2	EN 15662:2018	0.01	<0.01

The electronic version of new COA still has the Sino Silliker electronic signature and passes the validation, you can check the authenticity when you open the PDF version; all paper version will be printed on special COA paper, and put on special analysis cross-page stamp.

If you have any further question on the new COA, welcome to call our service hotline 400 627 8088, we will be at your service and thank you for your understanding and support!

## Focus on China



### Agriculture ministry sets compensation for pigs killed due to virus

The Ministry of Agriculture and Rural Affairs said over the weekend that hog producers affected by African swine fever are now eligible for compensation of 1,200 yuan (\$180) for each pig slaughtered due to the contagious virus.

Local authorities are encouraged to refine their compensation regulations in accordance with the specific size and breed of hogs that have been culled due to disease outbreaks, according to the Ministry.

The universal standard for the amount of compensation payment varies between 50 to 100 percent of market prices. The 1,200-yuan-per-head pay is about 75 percent of the average hog price in China, the Ministry said, adding that the amount was jointly decided with the Ministry of Finance.

To guarantee that hog farmers will receive compensation, the central leadership has dispatched extra funds dedicated to containing African swine fever, and issued annual funds allocated for prevention and control of animal diseases in advance.

China has reported more than 110 African swine fever outbreaks since the first case was confirmed in the northeast's Liaoning province in August.

The latest outbreak was confirmed on Saturday at two separate breeding farms in Lichuan, Central China's Hubei province. A total of 78 hogs were killed as a result.

## African swine fever 'under effective control': agriculture minister



China's African swine fever situation is now "under effective control" and growth of new cases is gradually slowing down, the country's agriculture minister said Tuesday.

A total of 122 cases of African swine fever had been reported by 30 provincial-level regions as of

Monday. Of the cases, 108 had ended blocks of the infected regions, Han Changfu, minister of agriculture and rural affairs, said while giving remarks at an international symposium in Beijing.

Production of live pigs and pork supply are generally stable, Han added.

China still faces a grave situation in African fever prevention and control due to factors such as the disease's properties and a rather dispersed pig-raising pattern in the country, Han pointed out.

The outbreak of the disease peaked last October and November and began to ease in December. Only 23 new cases have been reported since the beginning of 2019, according to Yu Kangzhen, deputy agriculture and rural affairs minister.

China has launched the highest level of emergency response for a major animal epidemic, established a monitoring network and introduced a string of supportive

policies to help pig farmers since the outbreak of the disease late last year. A comprehensive prevention and control mechanism is now in place.

Bukar Tijani, assistant director general of the Food and Agriculture Organization of the United Nations, observed that China has taken many concrete and effective measures in dealing with the epidemic and said it is encouraging to see the growth of new cases is slowing down in China.

China will keep implementing effective measures, enhance research and development on related vaccine and build a mechanism with long-term effects to strive for the eradication of the disease. Meanwhile, efforts will be made to balance epidemic prevention and control with live pig production and industrial transition to ensure stable supply.

Monique Eloit, director general of the World Organization for Animal Health, said China's experience, technology and measures used in controlling African swine fever can be shared with other countries to boost global capabilities in this field.

Han said efforts should be made to improve cooperation mechanisms, enhance prevention and control capabilities, and support international organizations in playing better roles.

## Number of foodborne outbreaks decreases in Hong Kong

There were more than 150 foodborne outbreaks affecting almost 650 people in Hong Kong last year.

Outbreaks concerning food premises and businesses were reported to the Centre for Food Safety (CFS) of the Food and Environmental Hygiene Department in 2018.

Food poisoning is a statutory notifiable disease in Hong Kong. With the Department of Health, the CFS is responsible for investigating and controlling outbreaks related to local

food premises and businesses.

CFS has referred 158 foodborne outbreaks affecting 641 people from the Department of Health. The annual number of referred cases has decreased slightly in the past few years.

Bacterial foodborne agents remained the leading causes (82 percent) of all outbreaks with *Salmonella*, *Vibrio parahaemolyticus*, and *Bacillus cereus* being the top three.

Viral causes accounted for around 12.7 percent of the outbreaks and all were related to norovirus. Inadequate cooking, contamination by raw food and improper holding temperature were the most frequently identified contributing factors.

Last year the CFS identified almost 2,000 food incidents from a system designed to monitor and review incidents that occurred outside Hong Kong. About 450 of these were recalls on the Food Incidents Surveillance System (FISS) related to undeclared allergens.



For incidents with local relevance, 46 percent of cases related to microbiological hazards, 33 percent to chemical, 15 percent to physical and 6 percent to others (e.g. substandard qualities).

From late February to mid-March 2018, six clusters of outbreaks related to a restaurant affecting 16 people were reported to the CFS. Stool specimens of two victims in two clusters were positive for *Salmonella enteritidis*. Epidemiological investigation of these clusters by the Department of Health suggested they were related to consumption of various dishes with stir-fried eggs on the same day.

An investigation found that unpasteurized eggs were used and cooked for a very short time before serving. Health advice was given to food handlers and the premises was advised to suspend the sale of food items and carry out thorough cleansing and disinfection. After irregularities such as inadequate cooking of food were rectified no further outbreaks were reported.

CFS advises trade to choose pasteurized eggs, egg products or dried egg powder to prepare dishes not requiring further heat treatment.

From late May to early June 2018, three outbreak clusters related to consuming products from a cooked food stall were reported to the CFS, with six people affected. Two victims submitted stool specimens for testing and both were positive for *Vibrio parahaemolyticus*.

The epidemiological assessment indicated the ready-to-eat food package with cooked cuttlefish and tofu was the possible source. Field investigation revealed products were marinated at room temperature for hours next to a working table for preparing raw seafood. Then they were packed and kept in a display showcase for sale until five to six hours later. The temperature of the display was measured at 29 degrees Celsius during the inspection.



Cross-contamination by raw food and improper holding temperature of cooked food may have contributed to the outbreak. Health advice was provided to the premises and sale of food items was suspended immediately. The site was thoroughly cleaned and disinfected. Follow up visits found no additional cases after the change of practices.

## International News

### FDA Issues Draft Guidance Regarding the Declaration of Allulose on the Nutrition Facts Label

The U.S. Food and Drug Administration issued a draft guidance today to provide its current view on the declaration of carbohydrates, total sugars and added sugars for products that contain allulose, a sweetener, on the Nutrition Facts label. The draft guidance also provides FDA's current view on calculating the caloric value of allulose. The guidance is designed to assist manufacturers in complying with the Nutrition Facts label requirements.

FDA is advising manufacturers that it intends to exercise enforcement discretion regarding the requirement that the sweetener allulose be included in the amount of Total Sugars and Added Sugars on the Nutrition Facts label. However, allulose still must be included in the amount of Total Carbohydrates. The draft guidance also advises manufacturers of its intent to exercise enforcement discretion regarding the use of 4 calories per gram of sweetener to calculate the caloric contribution of allulose and instead, allow manufacturers to use a caloric value of 0.4 calories per gram to calculate the caloric contribution of allulose.

Allulose is a low-calorie sweetener that is naturally occurring in small amounts in wheat, fruits such as raisins and dried figs, and in other sweet foods such as brown sugar and molasses. It can also be manufactured. While allulose has a

chemical structure similar to other sugars, it is not metabolized by the body in the same way as most sugars and does not contribute the same number of calories.

Under FDA's 2016 Nutrition Facts label rule, allulose must be included in declarations for Total Carbohydrates, Total Sugars, and Added Sugars. Current requirements also require allulose to be counted as 4 calories per gram of the sweetener. However, FDA stated in the final rule that additional time was needed to fully consider the science as to whether allulose should be excluded from these requirements. FDA has received several petitions related, in part, to whether allulose should be exempt from being included as a carbohydrate, sugar or added sugar and to the caloric value of allulose. This draft guidance conveys FDA's current thinking regarding allulose.

Nutrition Facts	
4 servings per container	
Serving size 1 1/2 cup (208g)	
Amount per serving	
<b>Calories</b>	<b>240</b>
% Daily Value*	
<b>Total Fat</b> 4g	<b>5%</b>
Saturated Fat 1.5g	8%
Trans Fat 0g	
<b>Cholesterol</b> 5mg	<b>2%</b>
<b>Sodium</b> 430mg	<b>19%</b>
<b>Total Carbohydrate</b> 46g	<b>17%</b>
Dietary Fiber 7g	25%
Total Sugars 4g	
Includes 2g Added Sugars	4%
<b>Protein</b> 11g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 6mg	35%
Potassium 240mg	6%

\* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

FDA will soon release other guidance documents regarding FDA's current views on the Nutrition Facts label requirements. As an example, FDA will finalize its draft guidance on declaring added sugars on honey, maple syrup and certain cranberry products.

Comments on the draft guidance should be submitted within 60 days after publication in the Federal Register of the notice announcing the availability of the guidance to ensure that they are considered before work begins on the final guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Dockets Management Staff

(HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2019-D-0725.

### FDA Grants Citizen Petition for Dietary Fiber

The U.S. Food and Drug Administration announced today that it intends to propose that “cross-linked phosphorylated RS4”—regardless of source—be added to the definition of dietary fiber. The action was taken in response to a citizen petition from MGP Ingredients Inc. Dietary fiber that can be declared on the Nutrition and Supplement Facts labels includes certain naturally occurring fibers that are “intrinsic and intact” in plants and added isolated or synthetic non-digestible soluble and insoluble carbohydrates that FDA has determined have beneficial physiological effects to human health.

The FDA established a definition for dietary fiber in its Nutrition Facts label final rule, which was published in the Federal Register on May 27, 2016. Based on available evidence, FDA has determined that the scientific evidence suggests that cross-linked phosphorylated RS4 can help reduce insulin levels following a meal containing a carbohydrate that raises blood glucose levels.

Including this current notification, 16 categories of non-digestible carbohydrates (e.g. mixed plant cell wall fibers, a broad category) are either included in the definition of dietary fiber or are non-digestible carbohydrates that FDA intends to propose to be added to the definition of dietary fiber (see Questions and Answers on Dietary Fiber for a list). Seven of these fibers were identified in the Nutrition Facts label final rule as meeting the dietary fiber definition. Until FDA completes rulemaking regarding adding additional fibers to the regulatory definition of dietary fiber, the agency intends to exercise enforcement discretion

to allow manufacturers to include the amount of these additional fibers in the dietary fiber declaration on the Nutrition and Supplement Facts labels. Firms can submit citizen petitions requesting that additional fibers be added to the definition of dietary fiber. Those petitions will be reviewed on a rolling basis.

### U.S., dozens of countries received cheese that was recalled for *Listeria* risk



The United States is one of more than 30 countries that received cheese from France potentially contaminated with *Listeria*.

*Listeria monocytogenes* was detected in Coulommiers, a type of cheese, from France. The product was part of a mass recall of raw and

pasteurized cheese made by Fromagère de la Brie.

Santé publique France, the public health agency, identified two cases of listeriosis in women who consumed cheese made by Fromagère de la Brie at its site of St Siméon, a village in Île-de-France.

A U.S. Food and Drug Administration spokeswoman confirmed to Food Safety News that the country had received some of the cheese.

“The FDA is aware of the issue and we are investigating with the cooperation of the firm’s U.S. agent. We are not aware of any illnesses at this time. The cheeses



exported to the U.S. are “Explorateur” and sold in three different sizes – 1 kilogram, 250 gram and 125 gram.”

In April 2018, Seacrest Foods International Inc. recalled 29 cases of l’Explorateur soft ripened cheese because it had the potential to be contaminated with *Listeria monocytogenes*. The Fromagère de la Brie brand, l’Explorateur, is a cheese made from pasteurized milk.

A few days later, World’s Best Cheeses of Armonk, NY, recalled 22 cases of the cheese for the same reason. The company said it was one of several importers notified of a potentially positive test result for *Listeria monocytogenes*. No illnesses were connected to either recall.

#### Global distribution

The current recall includes cheese that was sent to more than 30 countries including Australia, Austria, Belgium, Denmark, Germany, Hong Kong, Ireland, Italy, Japan, Jersey, Luxembourg, Macao, Mauritius, Myanmar, Netherlands, Norway, Oman, Philippines, Poland, Romania, Senegal, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, United Arab Emirates and the United Kingdom.

The Centre for Food Safety (CFS) in Hong Kong urged the public not to consume a type of cheese imported from France due to possible contamination with *Listeria monocytogenes*.

Cheese Brillat Savarin of the Bordier brand was imported by Classic Fine Foods (Hong Kong) Ltd. It has lot numbers 352702, 352203, 352802 and 352803 and best before dates from April 12 to May 7, 2019.

Preliminary investigation found the importer had 11 pieces of the affected

product and all of them had been distributed.

Another imported, K-Element Limited, had the same implicated product but with lot numbers 1900307B, 1900437B, 1901105, 1901542B, 1901757, 1901933B, 1902075B, 1902379B, 1902791 and 1903446B and best before dates Feb. 10 to April 21, 2019.

A recall in Australia was expanded to include Organic Spring Pty Ltd. products sold at Spring Street Cheese Cellar in Victoria.

Chaource St-Simeon 250 gram with best before dates of Feb. 24, March 24, April 14 and 28, 2019; Brie de la brie 3 kilogram with best before dates of March 1, 24 and April 14, 2019; and Explorateur Mini Sous Coque 125 gram with best before dates of Feb. 12, April 14 and 28, 2019 are affected.

#### Expansion of E. coli cheese recall

Meanwhile, a different recall from another French company of raw goat’s milk cheese has been expanded to include more countries.

Shiga toxin-producing E. coli O26 was detected and Jacquin recalled Pouligny Saint-Pierre raw milk PDO goat cheese with the brand name “P. Jacquin et Fils.”

Government officials reported other countries that received the cheese included Austria, Belgium, Denmark, Germany, Ireland, Japan, Netherlands, Portugal, Singapore, Spain, Sweden, Switzerland, the United Kingdom and Vietnam.

### **FSIS Proposes to Remove Dual Labeling Requirements for Certain Amounts of Meat and Poultry Products**

The U.S. Department of Agriculture’s (USDA) Food Safety and Inspection Service (FSIS) announced today that it is proposing to amend labeling regulations to

remove duplicative net weight and net content requirements for packages that contain certain amounts of meat or poultry products. The proposed regulation would apply to products that are at least one pound or one pint, but less than four pounds or one gallon.

FSIS is proposing this action after receiving a petition submitted by a small meat processor in response to USDA's request for ideas to better serve its customers.

“It's simply good government to review old regulations to see if they are outdated and burdensome,” said FSIS Administrator Carmen Rottenberg. “FSIS doesn't believe that a duplicative labeling requirement helps consumers and sees it as an unnecessary requirement for industry.”

Under proposed rule, establishments that produce meat and poultry products in packages containing one pound or one pint and less than four pounds or one gallon will be allowed to express the weight or contents in one unit of measurement on the product label, instead of using both measures [e.g., “Net Wt. 24 oz.” or “Net Wt. 1.5 lbs.” rather than “Net Wt. 24 oz. (1.5 lbs.)”].

Establishments would be allowed to use their current labels until they run out or may elect to use them indefinitely.

### EFSA Releases Scientific Opinion on Six-event GM Maize

Following the submission of application EFSA - GMO - DE - 2011 - 103 under Regulation (EC) No 1829/2003 from Syngenta, the Panel on Genetically Modified Organisms of the European Food Safety Authority (hereafter referred to as the ‘GMO Panel’) was asked to deliver a scientific opinion on genetically modified (GM) maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 (hereafter referred to as ‘the six - event stack maize’) and its subcombinations

independently of their origin (referred to hereafter as ‘subcombinations’). The scope of application EFSA - GMO - DE - 2011 - 103 is for the placing on the market of maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 and all its subcombinations independently of their origin for food and feed uses, import and processing.

The term ‘subcombination’ refers to any combination of up to five of the events present in the six - event stack maize. The safety of subcombinations occurring as segregating progeny in the harvested grains of maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 is evaluated in the context of the assessment of the six - event stack maize in Section 3.3 of the present GMO Panel scientific opinion. The safety of the subcombinations that either have been or could be produced by conventional crossing through targeted breeding approaches, which can be bred, produced and marketed independently of the six - event stack maize, are risk assessed in Section 3.4 of the present scientific opinion.

In delivering its scientific opinion, the GMO Panel considered the information available on the single events, the six - event stack maize, 25 of the subcombinations (10 two - event stacks, 10 three - event stacks, 4 four - event stacks and a five - event stack), the scientific comments submitted by the Member States and the relevant scientific literature. The six - event stack maize was produced by conventional crossing to combine six single maize events: Bt11 (expressing Cry1Ab and the phosphinothricin acetyl transferase (PAT) proteins); MIR162 (expressing the Vip3Aa20 and the phosphomannose isomerase (PMI) proteins); MIR604 (expressing a modified Cry3A (mCry3A) and the PMI proteins); 1507 (expressing the Cry1F and the PAT proteins); 5307 (expressing the eCry3.1Ab and the PMI proteins); and GA21 (expressing the 5 -

enolpyruvylshikimate - 3 - phosphate synthase enzyme (mEPSPS)). Herbicide tolerance traits are achieved by the expression of mEPSPS protein from *Zea mays* and PAT protein from *Streptomyces viridochromogenes*. Insect resistance traits are achieved by the expression of the Cry1Ab, Vip3Aa20 and Cry1F proteins from *Bacillus thuringiensis* for protection against specific lepidopteran pests and by the expression of the mCry3A and eCry3.1Ab proteins from *B. thuringiensis* for protection against corn rootworm (*Diabrotica* spp.) larval feeding.

The GMO Panel evaluated the six - event stack maize and its subcombinations with reference to the scope and appropriate principles described in its guidelines for the risk assessment of GM plants and derived food and feed, the environmental risk assessment of GM plants and the post - market environmental monitoring (PMEM) of GM plants.

For application EFSA - GMO - DE - 2011 - 103, previous assessments of the six single maize events Bt11, MIR162, MIR604, 1507, 5307 and GA21 and 22 of the subcombinations (10 two - event stacks, 9 three - event stacks and 3 four - event stacks), together with new information on three subcombinations, provided a basis to evaluate the six - event stack maize and all its



subcombinations. No safety concerns were identified by the GMO Panel in the previous assessments. No safety issue concerning the six single maize events was identified by the updated bioinformatic analyses, nor reported by the applicant since the publication of the previous GMO Panel scientific opinions. Therefore, the GMO Panel considers that its previous conclusions on the safety of the single maize events remain valid.

For the six - event stack maize, the risk assessment included the molecular characterisation of the inserted DNA and analysis of protein expression. An evaluation of the comparative analysis of agronomic/phenotypic and compositional characteristics was undertaken, and the safety of the newly expressed proteins and the whole food and feed were evaluated with respect to potential toxicity, allergenicity and nutritional characteristics. An evaluation of environmental impacts and the PMEM plan was also undertaken.

The molecular characterisation data establish that the events stacked in maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 have retained their integrity. Protein expression analyses show that the levels of the newly expressed proteins are similar in the six - event stack and in the single events or already assessed subcombinations, except for the expected higher levels of the PAT and PMI proteins in the six - event stack resulting from the combination of events Bt11 and 1507 (both producing PAT) and events MIR162, 5307 and MIR604 (all producing PMI). No indications of interactions that may affect the integrity of the events and the levels of the newly expressed proteins in this six - event stack maize are identified.

The comparative analysis of forage and grain composition and agronomic/phenotypic characteristics identified no differences between maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 and the non - GM



comparator that required further assessment for food/feed safety or environmental impact, except for the levels of ash, potassium, zinc,  $\beta$  - carotene, folic acid, methionine, arachidic acid (C20:0) and ferulic acid in grain and for the agronomic/phenotypic endpoints early stand count, final stand count, days to 50% pollen shed and grain moisture. All those changes were further assessed and not found to have a safety impact.

The molecular characterisation, the comparative analysis and the outcome of the toxicological, allergenicity and nutritional assessment indicate that the combination of the single maize events and of the newly expressed proteins in the six - event stack maize does not give rise to food and feed safety and nutritional concerns. The GMO Panel concludes that maize Bt11  $\times$  MIR162  $\times$  MIR604  $\times$  1507  $\times$  5307  $\times$  GA21, as described in this application, is as safe as and nutritionally equivalent to its non - GM comparator and the non - GM reference varieties tested.

Considering the events combined and their potential interactions, the outcome of the comparative analysis and the routes and levels of exposure, the GMO Panel concludes that maize Bt11  $\times$  MIR162  $\times$  MIR604  $\times$  1507  $\times$  5307  $\times$  GA21 would not raise safety concerns in the case of accidental release of viable GM maize grains into the environment.

Since no new safety concerns were identified for the 22 previously assessed subcombinations (10 two event stacks, 9 three - event stacks and 3 four - event stacks) and no new data leading to the modification of the original conclusions on safety were identified, the GMO Panel considers that its previous conclusions on these maize subcombinations remain valid. The remaining 34 subcombinations included in the scope of application EFSA - GMO - DE - 2011 - 103 have not been previously assessed; for three of them, the applicant provided

new information that was considered by the GMO Panel. The GMO Panel assessed the possibility of interactions between the events in the 34 subcombinations and concludes that these combinations would not raise safety concerns. These subcombinations are therefore expected to be as safe as and nutritionally equivalent to the single events, the previously assessed subcombinations and the six - event stack maize.

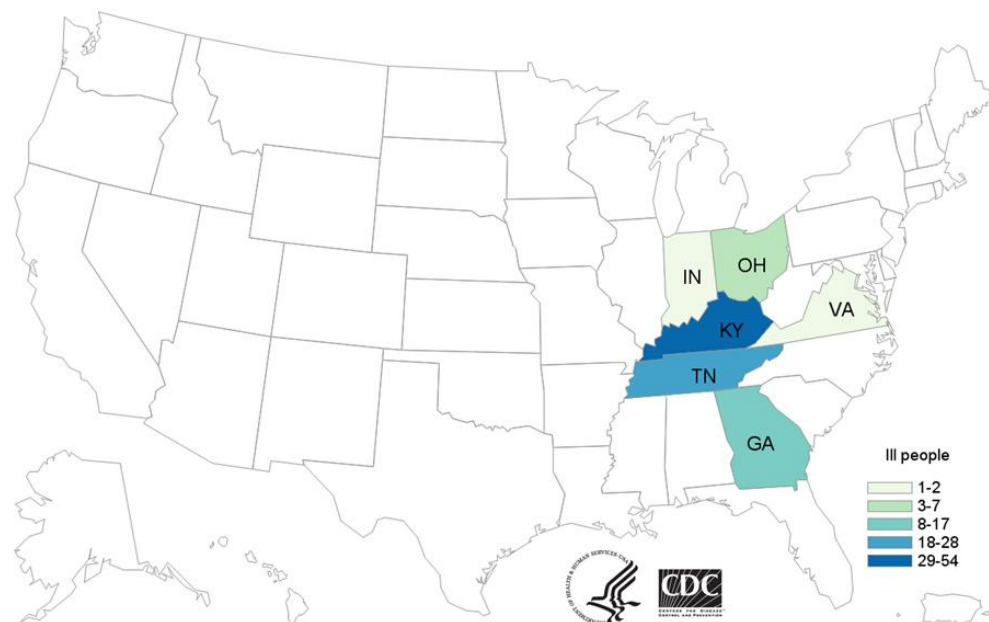
Given the absence of safety concerns for foods and feeds from maize Bt11  $\times$  MIR162  $\times$  MIR604  $\times$  1507  $\times$  5307  $\times$  GA21 and all its subcombinations, the GMO Panel considers that post - market monitoring of these products is not necessary. The PMEM plan and reporting intervals are in line with the intended uses of the six - event stack maize and its subcombinations.

### France Bans Titanium Dioxide Food Additive Beginning in 2020

On April 17, 2019, the Ministry of Ecological and Solidarity Transition issued a press release announcing that France will prohibit foods containing food additive E171 (titanium dioxide) from being placed on the market beginning January 1, 2020. The press release cites the April 15, 2019, opinion from the Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES). The expert group established by ANSES conducted a literature review on the oral toxicity of E171, identifying 25 studies published since 2017. ANSES concluded that it has no new information to remove the uncertainties regarding the safety of the E171 additive. Pending a better toxicological characterization of E171 and work currently underway at the European level, ANSES reiterates its previous general recommendations on nanomaterials aimed at limiting the exposure of workers, consumers, and the environment by promoting products that are safe and equivalent products in terms of function and efficiency, without nanomaterials. According to the

Ministry's press release, an order regarding the ban has been signed and will be published as soon as possible. As E171 is authorized at the European Union (EU) level, France will notify the order to the European Commission and other EU Member States, which will then meet within ten days.

### CDC suspects ground beef as source of expanding O103 outbreak



Ground beef, consumed at home or in restaurants, and possibly purchased in large packages from grocery stores just might be the source of the now six-state E. coli O103 outbreak, according to CDC.

In an update of its last report just three days earlier, the Centers for Disease Control and Prevention (CDC) in Atlanta shared its preliminary epidemiologic information that implicates ground beef for infecting at least 109 people.

In the three days since its last report, CDC reported 13 additional confirmed cases and added one additional state, Indiana, to the outbreak of the rare O103 E. coli strain.

The 109 illnesses reported by CDC are confirmed by the agency's PulseNet laboratory network as part of the O103 outbreak. The states are investigating additional cases that might also be a part of this outbreak.

Illnesses started on dates from March 2, 2019, to March 26, 2019. Ill people range in age from less than 1 year to 83 years, with a median age of 18. Fifty-three percent are female. Of 81 people with information available, 17 (21 percent) have been hospitalized. No deaths and no cases of the hemolytic uremic syndrome have been reported.

Illnesses that occurred after March 20, 2019, might not yet be reported due to the time it takes between when a person becomes ill with E. coli and when the illness is reported. On average, it takes two to three weeks.

### Investigation of the Outbreak

This multistate investigation began on March 28, 2019, when officials in Kentucky and Georgia notified CDC of this outbreak. Preliminary epidemiologic information suggests that ground beef is the source of this outbreak.

In interviews, ill people answered questions about the foods they ate and other exposures in the week before they became sick. Sixty-three (84 percent) of 75 people interviewed reported consuming ground beef. This percentage is significantly higher than results from a survey [Cdc-pdf\[PDF – 787 KB\]](#) of healthy people. Ill people bought or ate ground beef from several different grocery stores and restaurants. Many who became people bought large trays or chubs of ground beef from grocery stores and used the meat to make dishes like

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spaghetti sauce and sloppy joe.

Traceback investigations are ongoing to determine the source of ground beef supplied to grocery stores and restaurants where ill people ate. The agency also said:

- At this time, no common supplier, distributor, or brand of ground beef has been identified.
- CDC is not recommending that consumers avoid eating ground beef at this time. Consumers and restaurants should handle ground beef safely and cook it thoroughly to avoid foodborne illness.
- At this time, CDC is not recommending that retailers stop serving or selling ground beef.
- This is a rapidly evolving investigation. We will provide updates as more information becomes available.

CDC will provide more information as it becomes available.

## Safety Alerts

Date	Brand Name	Product Description	Reason/ Problem	Company
04/16/2019	Jensen Tuna Inc.	Frozen Ground Tuna	Potential for Salmonella	Jensen Tuna Inc.
04/15/2019	Hercules Candy	Cashew Brittle Bits	Undeclared Peanuts	Hercules Candy LLC
04/15/2019	Ben & Jerry's	Coconut Seven Layer Bar bulk and Ben & Jerry's	Undeclared Tree Nuts	Unilever

		Chunky Monkey ice cream		
04/13/2019	Chips Ahoy!	Chips Ahoy Chewy Cookie	May contain an unexpected solidified ingredient	Mondelēz Global LLC
04/01/2019	NadaMoo!	Strawberry Cheesecake Non-Dairy Frozen	Undeclared Almond	Little Red Rooster Ice Cream Company, d/b/a NadaMoo!
03/28/2019	Wholesome Pantry	Organic Nut Butters	May be contaminated with Listeria monocytogenes	Wakefern Food Corp.
03/28/2019	Thomas Hammer	Blueberry Bread	Undeclared Egg	Thomas Hammer Coffee Roasters Inc.





## Enterprise News

### French Listeria cases linked to cheese company

Several people in France are part of a Listeria outbreak linked to eating cheese made by one company.

Santé publique France, the public health agency, identified cases of Listeria infection in people who consumed cheese made by Fromagère de la Brie. Food Safety News has contacted the agency to confirm details of the outbreak.

The initial investigation led to the withdrawal from sale and recall of all cheese made from raw and pasteurized milk manufactured by Fromagère de la Brie on its site of St Siméon, a village in the French region Île-de-France.

Epidemiological, environmental and food traceability investigations are continuing to identify the origin of contamination.

Affected brand names are Fromagere de la Brie, Loiseau, Hennart, Beillevaire and Fromagerie du Dolloir.

Creams and cheeses were marketed until April 9, 2019, under different national brands and retail stores.

French authorities urged people with any of the affected products to not consume and return them to the place of purchase for a refund.

Some of the cheese was exported to Austria, Belgium, and Luxembourg where it has also been recalled.

All lots and dates from February 10, 2019 of Fromagere de la Brie branded Brie, Coulommiers, Chevre, Chatel, Marquise, Saint-Simeon, Vignelaits, Bayard, Jean

de Brie, Brillat-Savarin, Creme de France, Explorateur, Morin, Fromage a la Truffe d'été and Le coeur de la Fromagerie, Coulommiers 45 percent Reflet de France is part of the recall.

All dates of Loiseau branded Brie de Meaux, Brie de Melun, Brie le Montereau, Montereau Poivre, Coulommiers and Orvannais with lot codes starting FB19 are affected.

All lots and dates of Hennart brand Boule de Raisin, Brie Aux Brisures de Truffes, Brie a la Moutarde, Brie au Poivre, Brie de Chevre, Brie de Melun, Camembert Bleu d'Auvergne, Chanteraine, Coulommiers Jeune, Coulommiers Fourre Aux Noix, Cremeux au Poivre, Fleuricreme and Plateau du Voyageur are involved as well as certain Hennart brand Brie de Meaux AOP jeune and Brie de Meaux AOP half affine.

Some Brie, Brillat Savarin and Brie de Nangis of the Beillevaire brand and all dates and lots of Coulommiers of the Fromagerie du Dolloir mark are also implicated.

Listeriosis is a serious infection caused by Listeria monocytogenes. It can lead to serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems as well as miscarriages and stillbirths among pregnant women.

Symptoms include fever, muscle aches, and sometimes nausea or diarrhea. If the infection spreads to the nervous system, headache, stiff neck, confusion, loss of balance and convulsions may occur. The incubation period is usually one to two weeks but can vary between a few and up to 90 days.

## Unilever recalls Ben & Jerry's products for undeclared tree nuts



Unilever is recalling a limited quantity of Ben & Jerry's "Coconut Seven Layer Bar" bulk and Ben & Jerry's "Chunky Monkey" pints, because they may contain tree nuts including almonds, Brazil nuts, and hazelnuts that are not declared in the ingredient list or allergy information list, according to a recall notice posted on the Food and Drug Administration's website.

Persons who have an allergy or severe sensitivity to these undeclared tree nuts

run the risk of a serious or life-threatening allergic reaction if they consume the recalled products. According to the recall notice, both affected products have a "Contains Walnuts" and a "May contain other tree nuts" labeled on the back.

The affected Ben & Jerry's "Coconut Seven Layer Bar" bulk product is sold in 2.4-gallon tubs, with a Consumer UPC number of "076840104246" and best-by-date of "SEP1520BJ4."

The affected Ben & Jerry's "Chunky Monkey" pint is sold in a pint tub (473 mL), with a Consumer UPC number of "076840100354" and best-by-dates of "AUG2820BH2," "AUG2920BH2," or "AUG3020BH2."

The products were manufactured in the United States, and according to the recall, no product was shipped outside of the U.S. The affected "Chunky Monkey" pints were distributed nationwide and reached consumers through retail stores. The affected "Coconut Seven Layer Bar" bulk products were also

distributed nationwide and reached consumers through wholesale and Ben & Jerry's scoop shops.

According to the recall notice, "No other container sizes or best by dates of Ben & Jerry's products – besides these specific lots of Coconut Seven Layer Bar bulk and Chunky Monkey pints – are affected by this voluntary recall, including other Pint Slices, pints or any other products served in Ben & Jerry's franchised Scoop Shops."

The recall was initiated after an undeclared nut was found during the production operation; "Unilever has not received any reports of illness associated with this product, but the company is voluntarily recalling this product out of an abundance of caution." Unilever's ongoing investigation shows that the issue stemmed from an error from one of its nut suppliers. According to the recall notice, the situation has been remediated.

## FDA warns low-acid canned food processor

Marukyo Co. Ltd. of Japan is on notice from the FDA because of significant deviations from the Emergency Permit Control regulation, and the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation.

Staff from the Food and Drug Administration inspected the Hatagasaki, Japan location of Marukyo Co. Ltd. on September 13 through 14, 2018. They discovered the "serious violations" regarding the firm's Emergency Permit Control, and Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers, according to a March 14 warning letter made public by the FDA in recent days.

Marukyo Co. Ltd. manufactures, processes, and distributes a variety of Low-Acid Canned Food (LACF) Dorayaki products; which, “in various flavors consist of red bean paste sandwiched between two baked wheat cakes.”

“As a manufacturer of LACF products intended for export to the United States, you are required to comply with the Federal Food Drug and Cosmetic Act (the Act) and the Federal regulations relating to the processing of low-acid foods packaged in hermetically sealed containers,” according to the letter sent to Mr. Hiroo Sumi, President of Marukyo Co., Ltd.

Although the firm responded to the FDA on October 1, 2018, via email including a description of the corrective actions taken and responded to the FDA’s follow-up questions on December 6, 2018, the FDA’s evaluation revealed that the firm’s responses were not adequate.

The FDA noted the following, unresolved, significant violations:



- First, the firm failed to file the scheduled processes for each low-acid food in each container size to comply, with the FDA. These filings must occur not later than 60 days after registration and prior to the packing of a new product. According to the FDA, “these must include the processing method, type of retort or other thermal processing equipment employed, minimum initial temperatures, times and temperatures of processing, sterilizing value, or other equivalent scientific evidence of process adequacy, critical control factors affecting heat penetration, and source and date of the establishment of the process, for each product in each container size,” for LACF products. During the inspection, the FDA determined that the firm has manufactured, packed and distributed various LACF products without registering and filing scheduled processes with the FDA.
- Second, the FDA noted that the firm seals their finished products in reduced oxygen packaging, creating a hermetic seal. The firm stores their finished products at ambient room temperature after packaging, before being transported to a refrigerated warehouse. The firm explained to the FDA investigator that the products are then shipped frozen to the U.S. and further explained that when the frozen product arrives in the U.S., it is thawed, distributed refrigerated and stored in retail markets at ambient or refrigerated temperatures. The FDA noted, “Your labeling states ‘KEEP REFRIGERATED and consume within 90 days’. Consequently, it appears that your firm is not following the handling instructions on the labels of your products, in that you are not continuously maintaining the products under refrigerated conditions.”
- Third, regarding the firm’s products as low-acid foods and subject to requirements under the Act, “during our previous inspection conducted on



November 14-15, 2013, you provided pH values for your Dorayaki products,” as the firm’s products fall under the FDA’s Low Acid Canned Foods (LACF) regulations. The firm needs to have scheduled processes developed by a Process Authority.

- Additionally, the firm’s September 30, 2018, response to FDA inspection notes described the firm’s corrective measures, included modifying their label, and adding a requirement for refrigerated storage of their product. According to the warning letter, the FDA replied on November 27, 2018 with questions regarding the specific time limit from packaging to refrigeration and, whether there are any established critical control points (CCPs) in the firm’s HACCP plan for their Dorayaki products to cover labeling, or refrigerated storage or freezing after packaging while held at the firm’s facility.
- The FDA also requested documents such as the firm’s revised HACCP plan; “You responded on December 6, 2018, to our questions and provided documents including your revised HACCP plan.” The firm also stated that they thought there was no risk of *Clostridium botulinum* in their product because of their water activity values. The FDA noted that “although low water activity prevents the spores from germinating, it does not kill *Clostridium botulinum*. Commercial sterility is achieved by controlling the water activity and the application of heat to kill vegetative pathogens.”

Food companies are given 15 working days to respond to FDA warning letters. “You should take prompt action to correct the violations noted in this letter. Failure to do so may result in regulatory action by FDA without further notice, including, without limitation, seizure and injunction,” according to the warning letter.

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