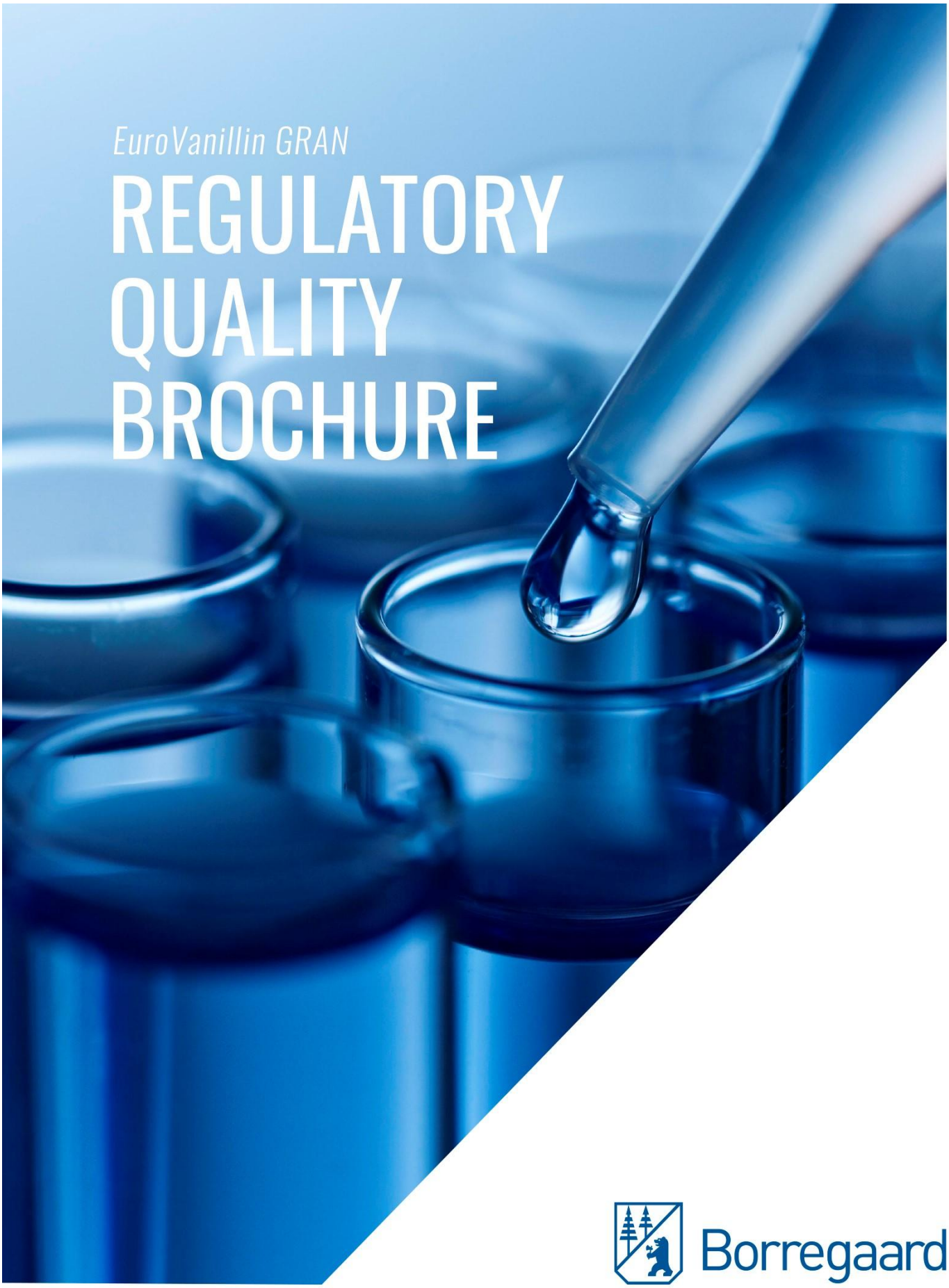


EuroVanillin GRAN

REGULATORY QUALITY BROCHURE

Borregaard

This document states and certifies the regulatory and quality aspects for the products in the Borregaard EuroVanillin GRAN range.

Learn more about our Vanillin range on **www.borregaard.com**

Borregaard AS

Name: Borregaard AS, Business Unit: BioVanillin
Head Office Address: Hjalmar Wessels vei 6, 1721 Sarpsborg, Norway
Homepage: www.vanillin.com
VAT ID number: 895623032

Emergency Contact: Borregaard 24-hour Security Office
Tel: +476911800

Borregaard

Table of contents

The GRAN range products 4
Regulatory compliance and food grade status 4
Certification 4
Labelling 5
Declarations 6
Nutritional content 6
Allergens 6
Microbiological content 7
Mineral and heavy metal content 7
FSMA compliance 8
Food fraud 9
Food defence 9
Foreign object control 10
Packaging food contact 10
Polycyclic Aromatic Hydrocarbons (PAHs) 10
Pesticide, mycotoxin (aflatoxin etc.), and dioxin 11
TSE/BSE 11
Proposition 65 status 11
GMO 11
Ionising radiation 12
Nano particles 12
Phthalates and plasticisers 12
Nitrosamines 12
Palm oil 13
Alcohol 13
Vegetarian and vegan 13
WADA 13
Non-animal origin 13
Animal testing 13
Manufacturing processes: 14
Packaging 15
Traceability 17

Borregaard

Hygiene and cleaning management 18

The GRAN range products

The EuroVanillin GRAN range consists of:

The products supplied by Borregaard comply with relevant regulations for food additives, e.g., EU Flavour and Hygiene Regulation (**Regulations (EC) No. 1334/2008** and **No. 852/2004**). The product is approved for use in food products as flavouring. For more information see the individual product specifications and safety data sheets which are all available on our website www.vanillin.com. Here you can also subscribe to updates and receive email notifications when new versions of the documentation are available.

Regulatory compliance and food grade status

The products supplied by Borregaard AS are manufactured and distributed in accordance with relevant regulations regarding food additives, e.g., comply with relevant regulations for food additives, e.g., **EU Flavour and Hygiene Regulation (Regulations (EC) No. 1334/2008 and No. 852/2004)** and the **US Code of Federal Regulations; 21 CFR § 172 and 182.** The products are considered to be of food grade and approved for use in food products as flavouring.

Certification

All of Borregaard's EuroVanillin products comply with the Food Safety System Certification; **FSSC 22000**. This is an ISO-based internationally accepted certification scheme for auditing and certification of food safety in the whole supply chain.

The system involves Hazard Analysis and Critical Control Points (**HACCP**), a management system for food safety. The products are controlled for biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.

The manufacturing site is also **ISO 9001** certified. ISO 9001 ensures that customers get consistent, good quality products and services.

Borregaard is certified according to **EcoVadis**. EcoVadis is the world's largest and most trusted provider of business sustainability ratings. They are dedicated to driving improvements in responsible and ethical business practices in global supply chains. Due to the way EcoVadis may change the status, Borregaard's level may also change, but our target is to always achieve the gold or platinum level. This means we are among the top 5% of the registered companies. Borregaard's EcoVadis registration number is: **CW732719**

All EuroVanillin GRAN products are **kosher**, and **halal** certified.

Labelling

EuroVanillin 3

Europe	When not intended for sale to final consumer, this product can be labelled as "natural flavouring substance" according to **Article 3(2)(c) in Regulation No. 1334/2008**.
USA	The product can be labelled as "natural flavour or natural flavouring" according to **21CFR101.22(a)(3)**.
Canada	The product can be labelled as "natural flavouring" according to Safe Food for Canadians Regulations, **SOR/2018-108 224 (1)**.

EuroVanillin 4

USA	The product can be labelled as "natural flavour or natural flavouring" according to **21CFR101.22(a)(3).**
Canada	The product can be labelled as "natural flavouring" according to Safe Food for Canadians Regulations, **SOR/2018-108 224 (1)**.

Declarations

Nutritional content

Flavourings are exempted from the requirement of the mandatory nutrition declaration given in section 3 of the food information regulation, e.g., annex V of **Regulation (EC) no. 1169/2011**. Dosages used in traditional food applications are very low and will not contribute to a measurable increase in nutrient content/energy in the customer's end product.

Allergens

In the context of the European **Regulation (EC) No. 1169/2011** and its subsequent amendments, general principles, requirements, and responsibilities governing food information to consumers, and in particular food labelling have been laid down. When used in the production of food and still present therein, certain ingredients or other substances or products (such as processing aids) can cause allergies or intolerances in some people and constitute a danger to the health of those concerned.

These substances causing allergies or intolerances, as listed in Annex II to this regulation, are part of the mandatory food information.

Allegrens and their derivatives	**Present in the product**
Celery	No
Cereals containing gluten (such as barley and oats)	No
Crustaceans (such as prawns, crabs and lobsters)	No
Eggs and egg products	No
Fish and fish products	No
Lupin	No
Milk and milk products (including lactose)	No
Molluscs (such as mussels and oysters)	No
Mustard	No
Peanuts	No
Sesame	No
Soybeans and their products	No
Tree nuts (almonds, hazelnuts, walnuts, brazil nuts, cashews, pecans, pistachios, and macadamia nuts)	No
Sulphur dioxide and sulphites (10 mg/kg or more)	No

The above-mentioned allergens and their derivatives are known to cause an allergic reaction as listed in Annex II of the EU Food Information for Consumers Regulation No. 1169/2011 and

Commission Delegated **Regulation (EU) No. 78/2014** amending **Annex II to regulation (EU) No. 1169/2011** and controlled in the facility to prevent cross contamination.

Based on our available data and information we have indicated by "Yes" or "No" whether or not a component is known to be present in the products. More information is available upon request.

Microbiological content

Determination of microbial contamination of the product is done by using known recognised analytical methods. Every batch is controlled for physical properties as colour, odour and purity. The production is routinely tested on a random selection of batches twice a year.

Analysis	Maximum expected level	Method
Aerobic (total) plate count	< 100 CFU/g	NMKL 86
Coliform bacterial 37°C	< 1 CFU/g	AFNOR 3M 01/02-09/89B
Escherichia coli	< 10 CFU/g	3M 01/8-06/01
Salmonella	Absent/25 g	BACGenePCR/ AFNOR EGS 38/01-03/15*
Yeasts	< 10 CFU/g	NMKL 98
Moulds	< 10 CFU/g	NMKL 98

NMKL: Nordic Committee on Food Analysis

*These are equivalent methods.

With a very low water activity (< 0,20 aw) and pH 4,6-5,3 the GRAN products are not reasonably likely to support foodborne pathogen growth even when products are held at optimum growth temperature. Therefore, the microbiological content is analysed twice per year.

Mineral and heavy metal content

The EuroVanillin GRAN products are sampled and analysed for other parameters, as minerals and heavy metals, twice a year. The analyses reports are available upon request. The products are also screened for pesticide contamination by using LC/MS/MS and GC/MS. The levels comply with regulatory requirements in the general food law. The limit of detection (LOD) and the limit of quantification (LOQ) for the methods are below the expected values.

Minerals	Maximum level	Method
Calcium (Ca)	0.75 %	ICP-MS
Phosphorus (P)	0.40 %	ICP-MS
Chloride (Cl)	0.20 %	Ion selective electrode
Sodium (Na)	0.10 %	ICP-MS
Iodine (I)	0.001 %	EN 15111
Metals, pesticides	**Maximum level**	**Method**
Lead (Pb)	< 1 ppm	ICP-MS
Copper (Cu)	< 0.5 ppm	ICP-MS
Cadmium (Cd)	< 0.5 ppm	ICP-MS
Arsenic (As)	< 0.05 ppm	ICP-MS
Mercury (Hg)	< 0.05 ppm	ICP-MS
Screening of pesticides	LOQ	LC/MS/MS and GC/MS

ICP= Inductively Coupled Plasma

The mineral, heavy metal and pesticide content is analysed twice per year.

FSMA compliance

Borregaard requires manufacturers of vanillin products to hold Food Safety System Certification recognised by GFSI, or to demonstrate Food Safety System practices at such level.

The manufacturing site maintains an FSSC 22000 certification for the manufacture of the GRAN products. The Food Safety Management System Manual includes the description of the system for establishing Food Safety Plans and includes assessment of threats (defense) and vulnerability (fraud).

Borregaard supplies customers in the USA and has assessed the relevant requirements introduced with the Food Safety Modernization Act.

- Current Good Manufacturing Practices are followed
- Trained Food Safety Team Leaders, acting as Preventive Controls Qualified Individuals are available
- A Food Safety Plan is implemented, and includes assessment of the following elements,
    1. Hazard Analysis
    2. Preventive Controls
    3. Recall Plan
    4. Monitoring, Verification, Validation
    5. Corrective Actions
- A Supplier Verification Program is implemented

Food fraud

Food fraud prevention is a part of FSSC 22000 requirements and therefore this topic is taken into account by Borregaard which is certified according to the FSSC 22000 scheme.

All policies, procedures and records are included in a food fraud prevention plan ongoing by Borregaard.

The main steps are:

- **Documented vulnerability assessment** on materials, suppliers and existing control measures that:
  - Identifies potential vulnerabilities,
  - Develops control measures to reduce or eliminate the identified vulnerabilities,
  - Prioritises control measures against the identified vulnerabilities.
- **Impact assessment**, to determine the potential risk of a food fraud event.
- **Mitigation plan** to reduce food fraud risk. The vulnerability to food fraud is mitigate through the topics below:
  - Raw materials specifications
  - Analytical surveillance
  - Supplier relationship
  - Supplier audit
  - Supply chain transparency and simplification

The food fraud plan has been prepared using a predefined structured process approved by Borregaard management and the plan is revised annually.

Food defence

Borregaard maintains a scheme to protect products and production processes from intentional harm, including from vandalism, sabotage, and terrorism.

Borregaard has established **requirements for suppliers and manufacturers of products**.

- Suppliers hold appropriate permits from authorities for operation/service provided.
- Manufacturers of products holds GFSI acknowledged Food Safety Certifications. In lack of such certificates, manufacturers will be audited by Borregaard.
- Warehouses hold appropriate permits from authorities for food storage.

The food defense plan includes maintenance and review of,

- Emergency Preparedness and Response Procedures
- Execution of, and learning from exercises

- Procedure for reporting of observations, and for implementation of verified corrective action
- Procedure for Change Management
- Programs put in place as measures to protect products and production processes

The food defense plan has been prepared using a predefined structured process approved by Borregaard management. Potentials have been carefully analysed, risks quantified, and measures put in place where found necessary.

The food defense plan complies with applicable legislation and is revised annually.

Foreign object control

In the production of the EuroVanillin GRAN products there are several critical control points (CCPs) that ensure the products are free from foreign contaminants:

- A glass and hard plastic policy with specific procedures and periodical inspections.
- A sieve with a screen size of 840 µm (20 mesh) is in place before packaging.
- A metal detector that checks the boxes before they are palletised. The metal detector has a sensitivity of 3.0 mm for non-Fe, 3.0 mm for stainless steel and 2.5 mm for Fe.

Packaging food contact

The EuroVanillin GRAN Products are packaged in material approved for food contact, conforming to the following regulations:

- **Regulation (EC) No. 1935/2004** on food contact materials – framework
- **Regulation (EC) No. 2023/2006** on GMP for materials articles intended to come into contact with food
- **Regulation (EC) No. 10/2011** on plastic materials food contacts and its subsequent amendments

Our declaration is based upon our suppliers' certificates and guarantees and is made in good faith and based on the current state of knowledge.

Polycyclic Aromatic Hydrocarbons (PAHs)

The EuroVanillin GRAN products do not contain Polycyclic Aromatic Hydrocarbons (PAHs).

Pesticide, mycotoxin (aflatoxin etc.), and dioxin

EuroVanillin GRAN products are subject to thorough analyses and there has never been found any detectable levels pesticides, mycotoxins (as e.g., aflatoxin), or dioxins. The pesticide content of the products is tested twice a year and the analyses report is available upon request.

TSE/BSE

The EuroVanillin GRAN products do not contain protein banned by **Regulation (EC) No. 999/2001** (last amended by **Reg. (EC) No. 1292/2005**) concerning certain protective measures regarding transmissible spongiform encephalopathies (TSE/BSE) and feeding of animal protein. This conformation is valid until revocation. Borregaard AS will inform the customer immediately if in the future changes are introduced to the manufacturing processes which affect the certified TSE/BSE status of the products.

Proposition 65 status

The Safe Drinking Water and Toxic Enforcement Act of 1986, better known as **Proposition 65**, are administered by The Office of Environmental Health Hazard Assessment (OEHHA). Proposition 65 establishes a list of chemicals which the state of California's risk assessment process has determined to present a risk of cancer or reproductive toxicity.

All substances on the Proposition 65 list (last updated September 13th, 2019) are not regularly monitored during the manufacture of Borregaard's products.

It is hereby stated that according to the best of our knowledge these substances are not contained, or are contained at negligible levels, in the EuroVanillin GRAN products.

GMO

Borregaard AS declare that the EuroVanillin GRAN products:

- Are manufactured in a manner where neither genetic modification technology nor genetically modified ingredients are used throughout the entire manufacturing process.
- Do not have to be labelled as GMO or containing GMO materials according to **Regulation (EC) No. 1829/2003** and **Regulation (EC) No. 1830/2003**, which authorises and regulates labelling and traceability of GMO and food derived products.

Borregaard is committed to providing GMO-free products. All the products we supply are manufactured, packaged, and labelled pursuant to the producers and standards set forth above.

Ionising radiation

Borregaard AS herewith confirm that the integrity of the EuroVanillin GRAN products are assured through manufacturing policies, including process HACCP evaluations, and process control mechanisms. These policies and processes cover all stages of product manufacture from raw material to through to finished product storage and customer delivery.

The EuroVanillin GRAN products have not been subjected to ionising radiation treatments as defined by **CFR 179.25** and **EU 1999/3/EC** during the manufacturing processes.

Nano particles

Borregaard AS declare that the EuroVanillin GRAN products do not contain nano materials and are not produced in the form of nano particles and follow the guidelines in **EU 696/2011**.

Phthalates and plasticisers

Borregaard AS hereby confirms that the EuroVanillin GRAN products do not contain any phthalates or plasticisers, eg. DEHP, DINP, DNOP, DIDP, DBP, BBP, DCHP, diphenyl phthalate, DNP, DBEP, BMPP, DBEP or BPA.

Nitrosamines

Nitrosamines are not regularly monitored during the manufacture of our products. According to our general knowledge about our EuroVanillin GRAN products, it is unlikely that such substances are formed during production or are contained at significant levels in our raw materials.

Borregaard AS therefore claim that, according to the best of our knowledge, the EuroVanillin GRAN products are not a potential source of nitrosamine impurities in the manufacture of pharmaceuticals.

Palm oil

Borregaard AS hereby confirms that the EuroVanillin GRAN products do not contain any palm oil or ingredients originating from palm oil.

Alcohol

The EuroVanillin GRAN products do not contain alcohols, nor is alcohols used in the manufacture of the products.

Vegetarian and vegan

The EuroVanillin GRAN products can be considered vegetarian and vegan according to all relevant definitions and interpretations of the terms vegetarian and vegan. The products are suitable for vegetarian and vegan diets.

WADA

the EuroVanillin GRAN products are not listed as prohibited substances by the World Anti-Doping Agency.

Non-animal origin

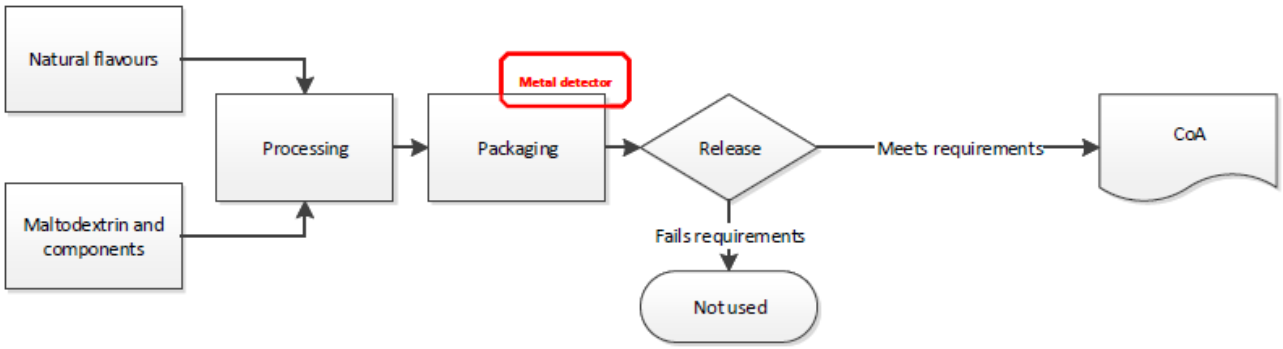
The EuroVanillin GRAN products have been chemically synthesised and do therefore not contain any animal or cell structure derived products. Nor are they derived from any animal or cell structure derived products.

Animal testing

The EuroVanillin GRAN products are not subject to animal testing, and animal testing is not part of the analysis performed on the products.

Manufacturing processes:

MANUFACTURE OF GRAN 3 & 4



Borregaard

Packaging

The EuroVanillin GRAN products are packaged as follows: An inner heat-sealed PE bag containing 25 kg of product placed in a cardboard box sealed with tamperproof logo tape. The packaging material used is approved for food contact conforming to all relevant regulations worldwide. There are 16 boxes and 400 kg of product per pallet.

Description	Composition	Weight	Dimensions	Number of units per pallet
Cardboard box	Kraft paper	910 g	38,3x46,5x27,1 cm	16
Label	Paper	2 g	23,9x15,4 cm	16
Pallet	Wood	13 kg	120x80x13,5 cm	1, one way, new
Film	PE	850 g		1
Tape		15 g		16
Kraft underlayer	Kraft paper	310 g	115x75 cm	1
Inner plastic bag	PE, heat sealed	130 g	38x105 cm	16

Traceability

The EuroVanillin GRAN products can be traced both up- and downstream by way of their batch numbers. The traceability is tested minimum once per year with mock recalls. Batch numbers can be decoded as follows:

NXXXXX-YYQQPBBBB SAP *Material number*

NXXXX X	N= 1 indicates that the material is a finished product N= 2 indicates that the material is a semi-finished product
YY	The two last digits in the year of manufacture
QQ	States the quality (“FC”, “FB”, “FE” etc.)
P	Type of product
BBBB	Serial number from 0001 to 9999 per product quality, independent of year

Example: 100696-20FCL1991
100696: SAP number
20: Year of manufacture
FCL: Product code
1991: Batch number

Hygiene and cleaning management

There are written instructions regarding health and personal hygiene and food safety rules (especially in clean packaging area) available.

Hygiene and internal audits are performed in critical areas, including the packaging areas, with a defined frequency according to according to FSSC 22000. The operators are trained on personal hygiene rules and refreshing courses are held on a regular basis.

There are cleaning and sanitizing procedures in place. The cleaning products that are used are food safe and appropriate for the applications. The cleaning monitoring programs include equipment, walls, floors, and surfaces which the products may come in to contact with. Their effectiveness is checked. Records are kept.

Environmental monitoring studies have been completed and performed regularly (on specific equipment and devices in contact with the operators).

Borregaard