

**A successful industry application:
Fruit Preparations
Pasteurised Using a High-Pressure
Treatment Process**

COMMISSION DECISION

of 23 May 2001

authorising the placing on the market of pasteurised fruit-based preparations produced using high-pressure pasteurisation under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2001) 1462)

(Only the French text is authentic)

(2001/424/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients⁽¹⁾, and in particular Article 7 thereof,

Having regard to the request by Groupe Danone to the competent authorities of France of 3 December 1998 for placing pasteurised fruit-based preparations produced by high-pressure pasteurisation on the market as a novel food ingredient,

Having regard to the initial assessment report drawn up by the competent authorities of France, which the Commission forwarded to all Member State on 16 May 2000.

Whereas:

- (1) In their initial assessment report the French competent food assessment body came to the conclusion that high-pressure treatment (8 kbar for 6 minutes at 20°C) may be safely used instead of the specified generally used heat pasteurisation process (85°C for 10 minutes).
- (2) Within the 60 days' period laid down in Article 6(4) of the Regulation, reasoned objections to the marketing of the product were nevertheless raised in accordance with that provision. In accordance with Article 7 of the Regulation, a Decision is therefore to be taken in accordance with the procedure laid down in Article 13 of the Regulation.
- (3) At a meeting on 9 October 2000 experts of Groupe Danone were called upon to provide the necessary information in response to the comments and objections raised by Member States. In particular, a technical explanation was given that the high-pressure treatment provides the same level of safety as the generally used heat pasteurisation process with respect to the bacteriological risks and the allergenic potential.

(4) It is therefore considered that the use of high-pressure pasteurisation in the production of fruit preparations is not likely to have an effect on public health so that a decision can be taken without consultation of the Scientific Committee for Food.

(5) On this basis, it is established that the products comply with the criteria laid down in Article 3(1) of the Regulation.

(6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DECISION:

Article 1

The fruit preparations pasteurised by high-pressure treatment, as specified in the Annex, may be placed on the market in the Community as a novel food ingredient.

Article 2

Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, the wording 'pasteurised by high-pressure treatment' is displayed next to the fruit preparations in question as such and in any product in which it is used.

Article 3

This Decision is addressed to Groupe Danone, 7 rue de Téhéran, F-75391 Paris CEDEX 08.

Done at Brussels, 23 May 2001.

For the Commission
David BYRNE
Member of the Commission

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.

Consumer Benefit

- Taste
- Colour
- Flavour
- Nutrition
- Palatable Technology

Products Marketed		
Product	Manufacturer	Country
Guacamole	Avomex	USA
Jams, fruit sauces salad dressings, jellies, fruit yoghurts	Meidi-Ya	Japan
Fruit juices	Pampryl	France
Fruit juices	Minute Maid	USA
Delicatessen-style hams	Espuña	Spain

Summary of Scientific Studies Conducted to Support Application

- Detailed physico-chemical characterisation
- Cytotoxicity (mouse fibroblasts)
- Mutagenicity (Ames Salmonella reversion assay)
- Impact of high-pressure treatment on allergenic risk
- Microbial challenge tests
- Contact material migration tests
- HACCP plan

Primary Objective

“At least as safe as conventionally processed products”

Summary of Results

- Non-cytotoxic
- Non-Mutagenic
- Equivalent or improved stability of vitamins C, B2, B6
- Organoleptic properties superior to conventional product
- Equivalent with respect to destruction of bacteria tested in vegetative state
- Bacterial spores are resistant to the pressures employed and risk management, as in conventional process, is based on prevention of germination/growth

Summary of agronomic and manufacturing conditions

Growing and Selection

Harvesting

Cleaning and immediate freezing

Storage at a maximum of -20°C for at least 15 d

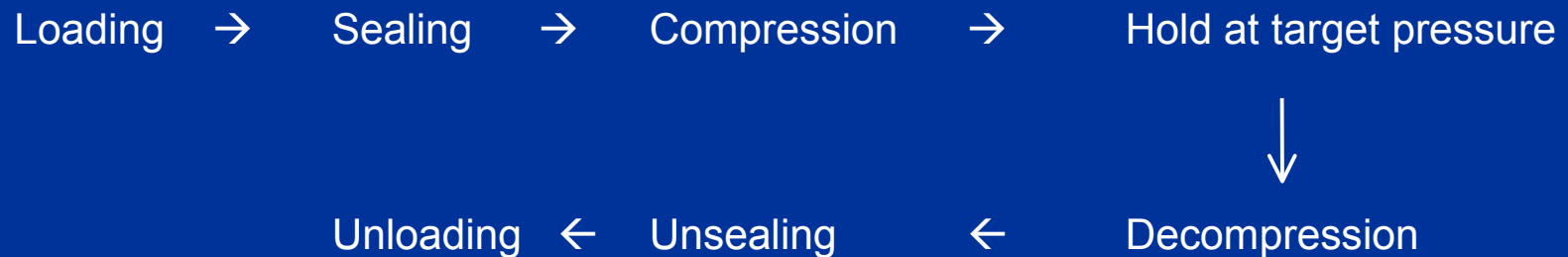
Thawing and mixing with other ingredients

Packaging

HP Process: 8.0 ± 0.1 kbar x 6 min at $20 \pm 2^{\circ}\text{C}$

Refrigerated storage at 5°C max for 60 d max

Sequence



Formula (based on strawberry)	%
Sliced Fruit	55
Sucrose	17.32
Glucose syrup	17.70
Xanthan gum	0.10
Pectin	0.25
Modified starch	2.50
Trisodium citrate	0.07
Flavouring	0.4
Colorants	0.182
Water	6.48

Physico-chemical properties (based on strawberry)	
pH	3.6 ± 0.2
° Brix	38 ± 2
Aw	0.94 ± 0.02

Microbial Challenge Tests

Class of organism	Species	Load before Cfu/g	Load after Cfu/g	Reduction
Yeasts	Candida haemulonii	3.1×10^7	<10	6 Log +
	Clavispora lusitaniae			
	Debaryomyces hansenii			
	Pichia membranae faciens			
	Saccharomyces cerevisiae			
Moulds	Aspergillus niger	1.6×10^5	0	5 Log +
Bacteria	E. coli 0157	3.1×10^4	0	4 Log +
	Listeria monocytogenes			
	Bacillus cereus			
	Salmonella typhimurium			
	Staphylococcus aureus			
Viruses	Hepatitis A	10^6	10^2	4 Log
	Rotavirus	10^6	0	6 Log
	Adenovirus	10^6	0	6 Log
Parasites	Cryptosporidium parvum	800,000/6g		96% decrease

Cyanogenic glycosides

- Regardless of plant tissue glycosidase activity, the presence of cyanogenic glycosides in significant quantities in human food is undesirable
- Cyanogenic glycosides are localised in the stones of fruits such as apricot, plum, cherry, peach and apple
- Stones are removed prior to HP processing
- The HP process as described does not change the risk of exposure to cyanogenic glycosides or to HCN

UK ACMSF (1992, 1995) Recommendations on preventing growth and toxin production by psychrotrophic *C. botulinum*

Maintain chill temperatures throughout the cold chain (10°C) +
(Singly or in combination):

- 90°C x 10 min or equivalent
- pH < 5.0
- $a_w < 0.97$
- Salt addition (to > 3.5% w/w in aqueous phase)

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 - 90°C x 10 min or equivalent
 - ✓ pH < 5.0
 - ✓ $a_w < 0.97$
 - Salt addition (to > 3.5% w/w in aqueous phase)
 - ✓ High pressure process to destroy vegetative cells

“ Products properly formulated to pH 4.6 or less have an excellent safety record and this is still recognized as the limit for safety of ambient products with respect to *C. botulinum*”

Bell and Kyriakides (2000), *Clostridium botulinum: a practical approach to the organism and its control in foods*, Blackwell Science.

Summary of Intended Manufacturing Conditions

- To be used only for previously frozen products (min -20°C x 15d)
- Fruit preparations only with specified physico-chemical characteristics (pH 3.2 – 4.2, °Brix 7 – 42)
- Process for intermediary product, with cold chain under manufacturer's control
- Storage at 5°C max for 60 d max
- Incorporation into finished product

Representative pH values of fresh fruit (ICMSF, 1998)

Fruit	pH range
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Apple	2.9 – 3.6
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Blackberry	3.0 – 4.2
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Fig	4.8 – 5.0
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Grapefruit	2.9 – 3.4
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Mango	3.8 – 4.7
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Orange	3.0 – 4.0
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Pear	3.4 – 4.7
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Raspberry	2.9 – 3.5
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Fruit	pH range
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Apricot	3.3 – 4.4
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Cherry	3.2 – 4.0
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Grape	3.0 – 4.5
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Lemon	2.2 – 4.5
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Melon	6.2 – 6.7
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Passionfruit	1.9 – 2.2
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Pineapple	1.9 – 2.2
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Strawberry	3.0 – 3.6
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ANNEX: Specification for fruit preparations intended for high-pressure pasteurisation

Parameter	Target	Comments
Types of Fruit	Apple, Apricot, Banana, Blackberry, Blueberry, Cherry, Coconut, Fig, Grape, Grapefruit, Mandarine, Mango, Melon, Peach, Pear, Pineapple, Prune, Raspberry, Rhubarb, Strawberry	Fruit used in conventional process
Fruit storage	Minimum 15 days at -20°C .	Fruit harvested and stored in conjunction with Good/Hygienic Agricultural and Manufacturing Practices.
Fruit added	40 – 60 % of thawed fruit	Fruit homogenised and added to other ingredients
pH	3.2 – 4.2	
$^{\circ}$ Brix	7 - 42	Assured by added sugars
a_w	< 0.95	Assured by added sugars
Final storage	60 days max at $+5^{\circ}\text{C}$ max	Equivalent to storage regimen for conventionally processed product.