Notification Number: 2001/76/F

Draft Decree on cells of human origin and on products of gene and cell therapies of human or animal origin with regard to the conditions for authorising the establishments and bodies carrying out the activities governed by Articles L.1243-1 and L.1261-2, the conditions for authorising the processes and products specified in Articles L.1243-6 and L.1261-3 and the conditions for authorising the clinical trial protocols specified in Articles L.1125-1 and L.1125-4.

Date received	:	09/02/2001
End of Standstill	:	20/02/2001
Invocation of the Emergency Procedure	:	Yes

Message

Departement of Trade and Industry - Stan dards and Technical Regulations - Dir 2
Mrs Brenda O'Grady

EFTA Surveillance Authority
Ms Solveig Georgsdottir

ELOT
Mr E. Melagrakis

European Free Trade Association
Ms Anne-Lise Bakke-D'Aloya

Kauppa-ja teollisuusministeriö
Mr Petri Kuurma

Kommerskollegium
Fru Kerstin Carlsson

Min. of Industry, Energy & Technology
Mr K. Polychronidis

Ministerie van Financiën - Belastingsdie nst - Douane / CDIU
De Heer IJ.G. van der Heiden

NSAI
Mr Tony Losty

Représentation Permanente de l'Irlande
.

Représentation Permanente du Royaume-Uni
.

Message 002

Communication from the Commission - SG(2001) D/50379
Directive 98/34/EC
Translation of the message 001
Notification: 2001/76/F

(MSG: 200100379.EN)

1. Structured Information Line
MSG 002 IND 2001 0076 F EN 09-02-2001 F NOTIF

2. Member State
FRANCE

3. Department Responsible
Délégué interministériel aux normes : 64-70 allée de Bercy- Télédoc 811-75574-Paris-Cedex 12

3. Originating Department
Secrétariat d'Etat à la santé
Direction générale de la santé
Sous-direction de la politique des produits de santé
Bureau des produits de santé d'origine humaine
1 Place de Fontenoy-75700-Paris
Personnes référentes :
Madame Liffran - tél. : 01-40-56-50-61
Monsieur Faucon tél. 01-40-56-52-03

4. Notification Number
2001/76/F - COOP

5. Title
Draft Decree on cells of human origin and on products of gene and cell therapies of human or animal origin with regard to the conditions for authorising the establishments and bodies carrying out the activities governed by Articles L.1243-1 and L.1261-2, the conditions for authorising the processes and products specified in Articles L.1243-6 and L.1261-3 and the conditions for authorising the clinical trial protocols specified in Articles L.1125-1 and L.1125-4.

6. Products Concerned

- products of cell therapy: cells of human or animal origin having undergone certain transformations (selection - sorting - multiplication - expansion) for the purpose of giving them therapeutic properties prior to transplanting or administering them to a patient registered in a cell therapy protocol (therapeutic technique consisting of transplanting to or injecting into a recipient autologous cells (from the recipient's own body), allogeneic cells (from a third party donor) or xenogeneic cells (of animal origin)).
- product of gene therapy: product intended to alter the genetic material of cells by introducing into them a gene which is intended either to correct a genetic disease or to modulate certain biological responses of the cells.

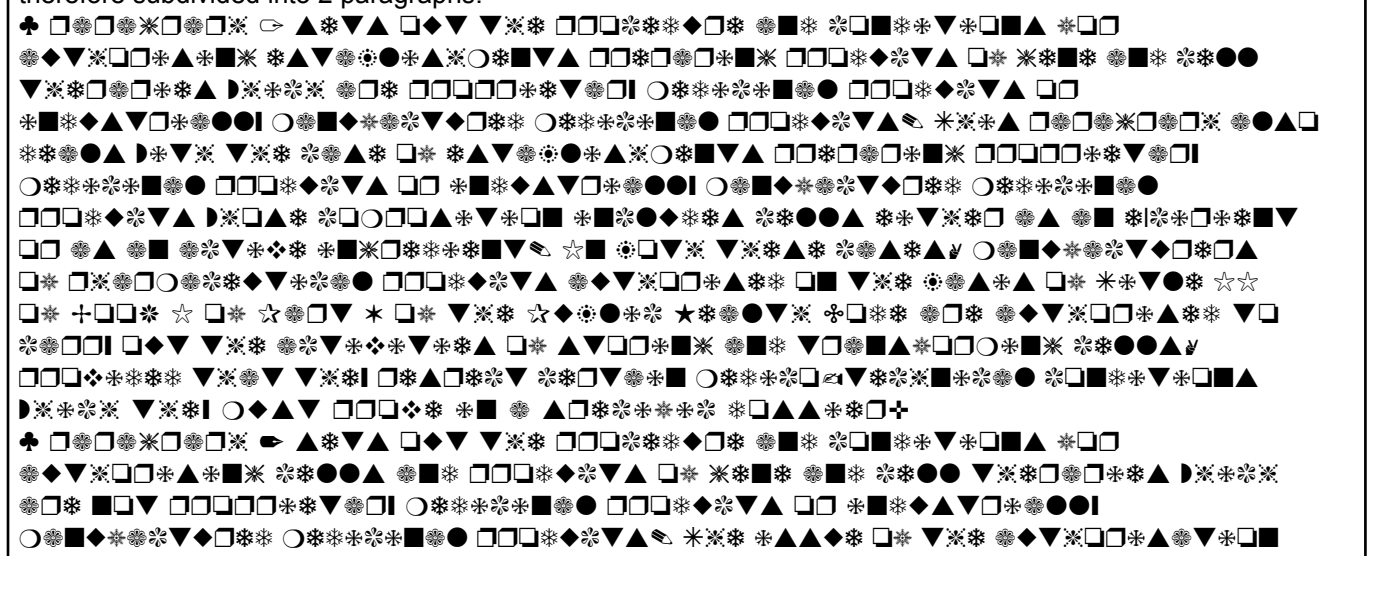
7. Notification Under Another Act
No

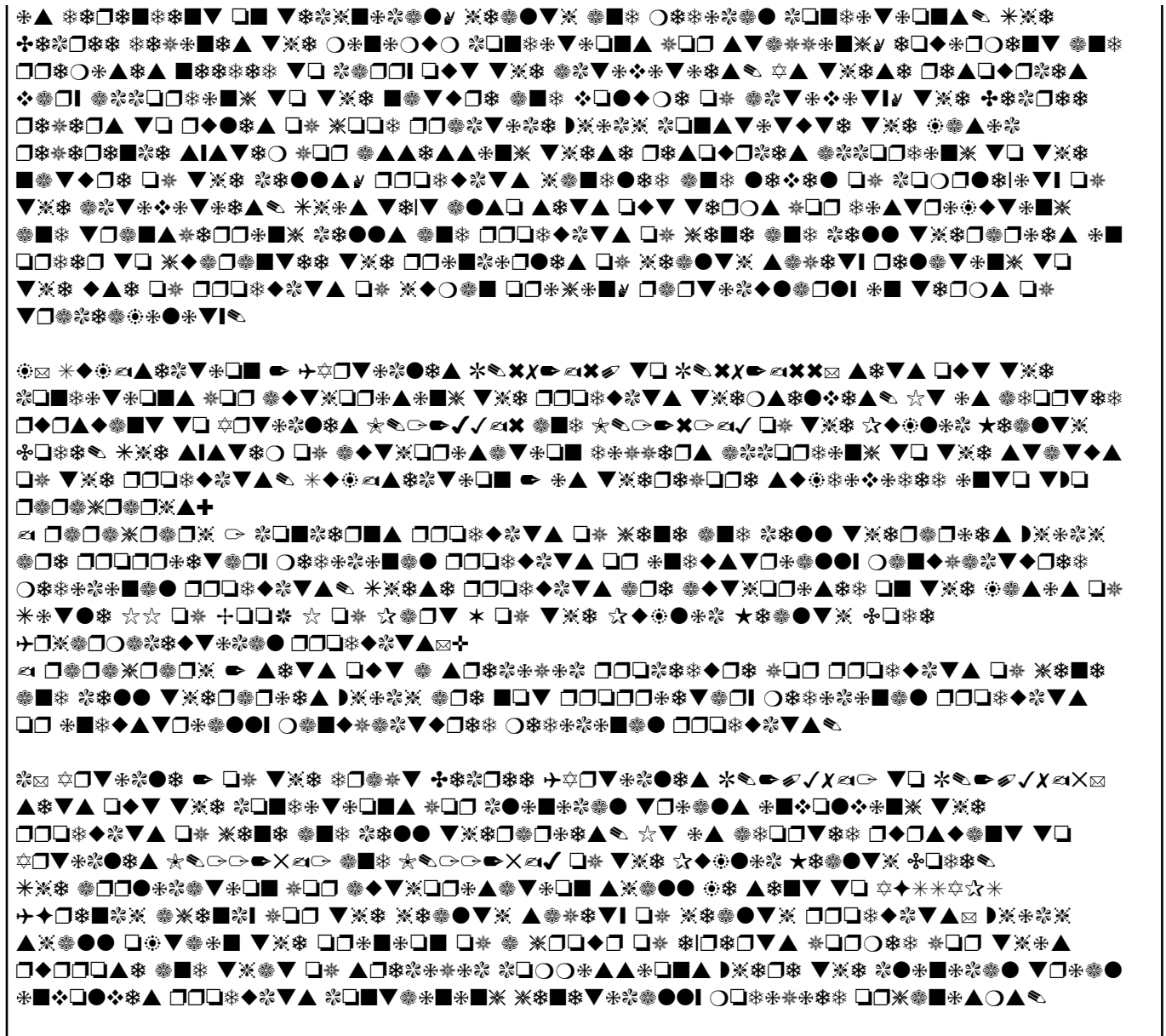
8. Main Content
This text is adopted pursuant to Articles L.1243-1, L.1261-2, L.1243-6, L.1261-3, L.1125-1 and L.1125-4 of the Public Health Code.
These various legislative provisions provide for, in the field of cells and products of gene and cell therapies, the implementation of certain regulatory provisions intended to authorise the activities which to date have been carried out without any particular supervision. This draft Decree therefore sets out the terms and conditions for authorising:

- the establishments and bodies carrying out the activities of preparing, transforming, storing, distributing and transferring the products of gene and cell therapies;
- the products themselves;
- the clinical trials.

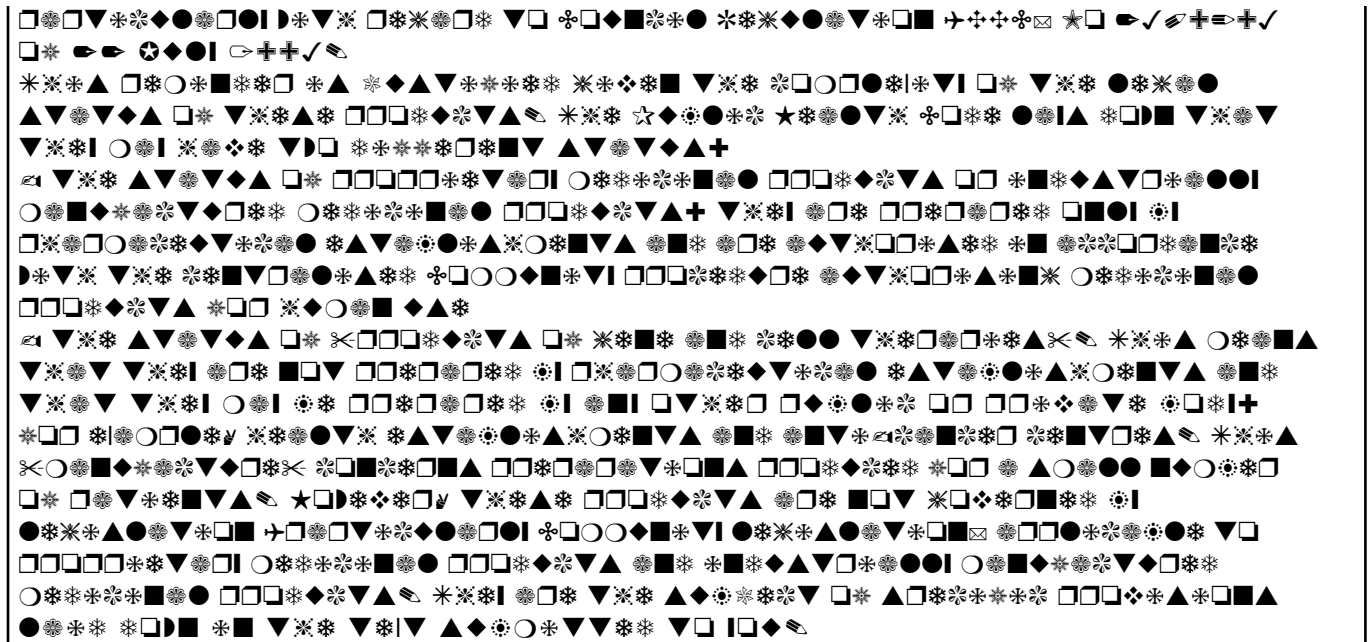
a) Sub-section 1 (Articles R.672-40 to R.672-59) sets out the conditions for authorising the establishments and bodies carrying out the activities of preparation, transformation, storage, distribution and transfer. It is adopted pursuant to Articles L.1243-1 and L.1261-2 of the Public Health Code.

The system of authorisation differs according to whether or not the products of gene and cell therapies have the status of proprietary medicinal products or industrially manufactured medicinal products. Sub-section 1 is therefore subdivided into 2 paragraphs:



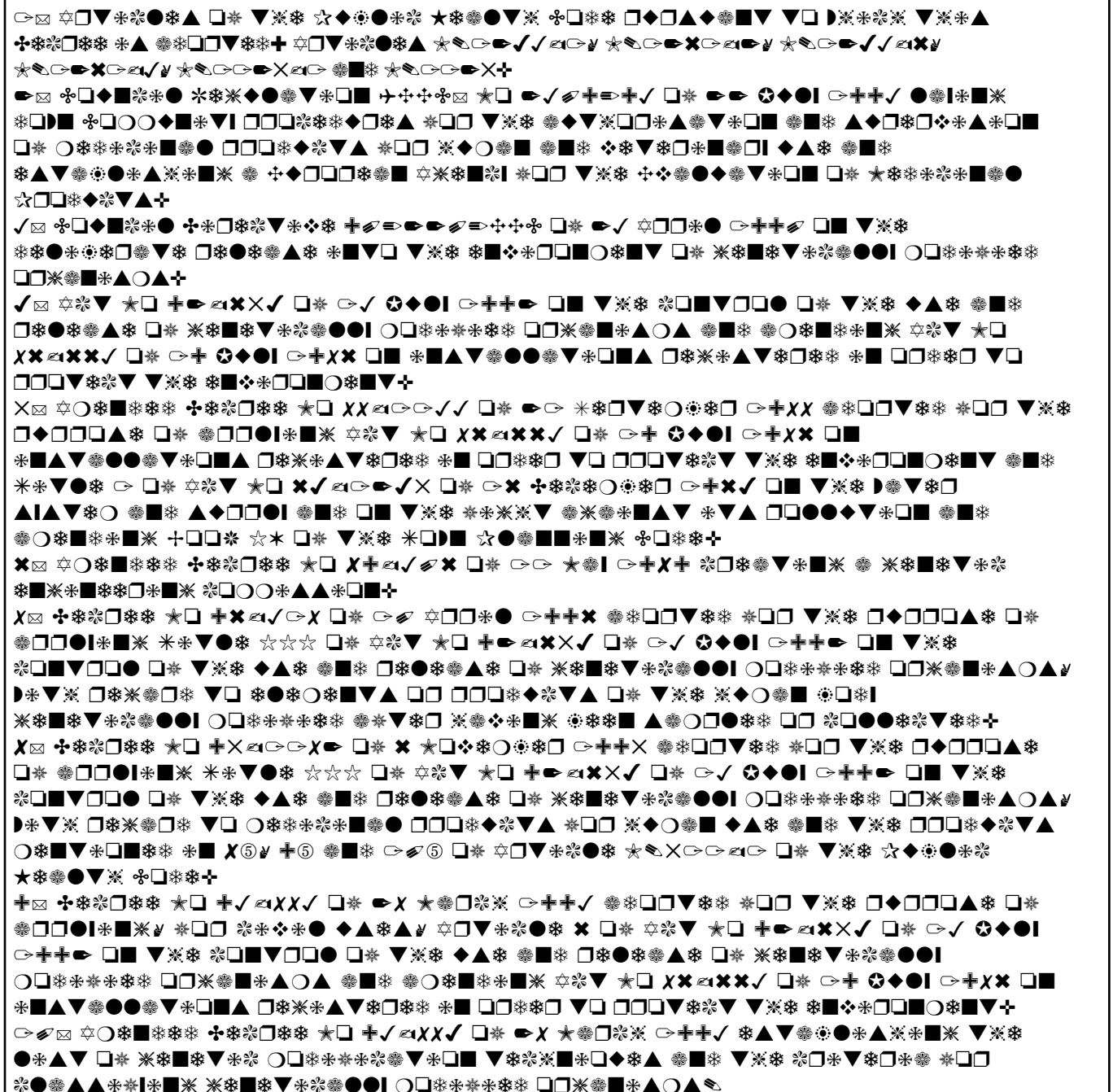


8. Main Content



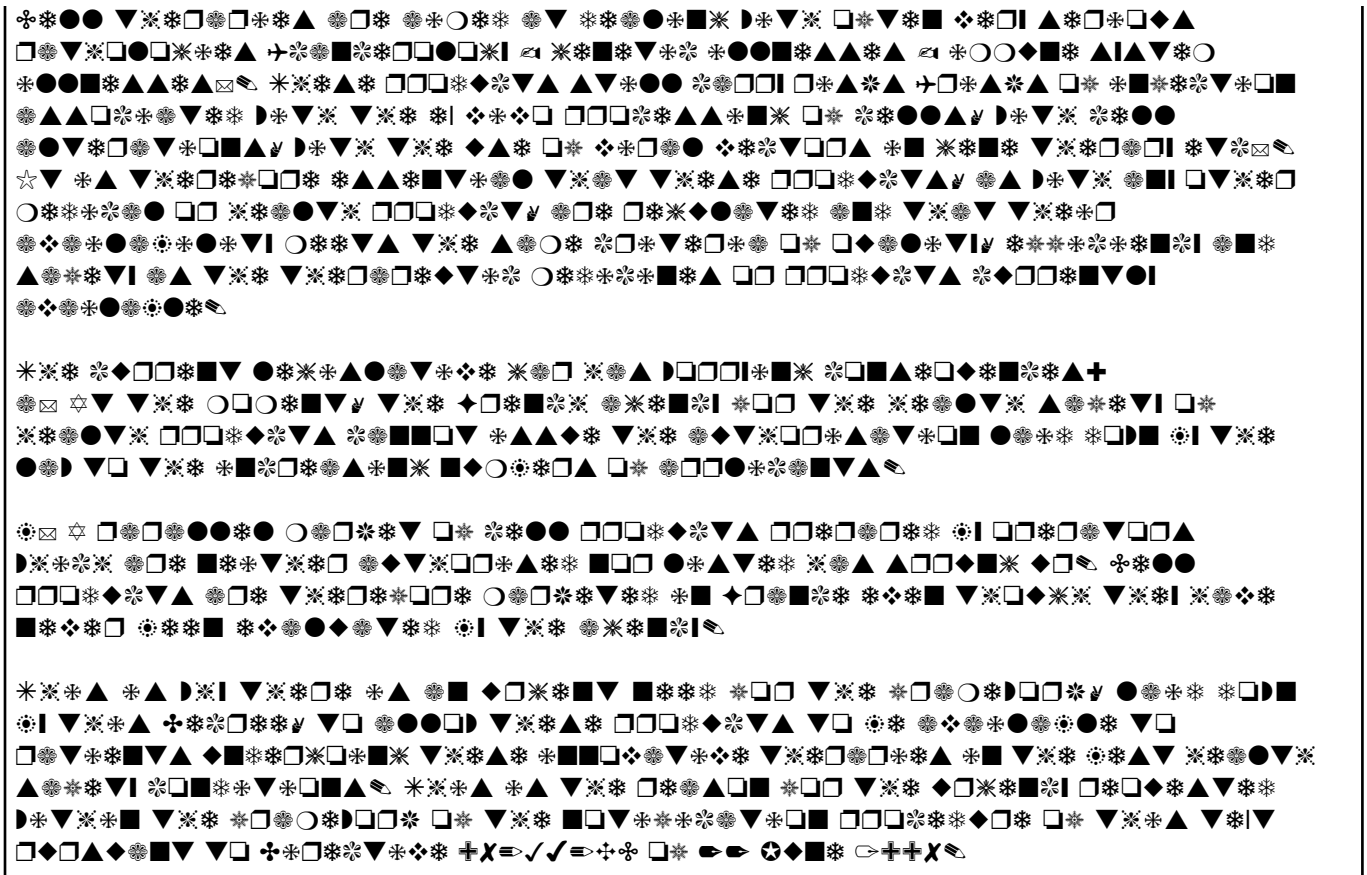
9. Brief Statement of Grounds

10. Reference Documents - Basic Texts



11. Invocation of the Emergency Procedure

12. Grounds for the Emergency



13. Confidentiality

14. Fiscal measures