



Notification Number: 1998/65/F

Proposal for a law on reinforcing health monitoring and hygienic safety testing of products intended for human consumption

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Issue of comments by : Commission, Denmark, Sweden
Issue of detailed opinion by : Belgium, Finland, Germany, Ireland, Netherlands, Portugal, Spain, United Kingdom

Message

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TELEX 002

COMMUNICATION FROM THE COMMISSION - SG (98) D/50329/2
DIRECTIVES 83/189/EEC, 88/182/EEC AND 94/10/EC
TRANSLATION OF TELEX 001
NOTIFICATION 98/0065/F

- 3B1 : 9800329.EN

1. Structured Information Line

TLX 002 IND- 98 0065 F-- EN ----- 980204 --- ---

2. Member State

France

3. Department Responsible

Secrétariat Général du Comité Interministériel
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3. Originating Department

Secrétariat d'Etat à la Santé - Direction Générale de la
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8, avenue de ségur - 75007 PARIS

4. Notification Number

98/0065/F

5. Title

Proposal for a law on reinforcing health monitoring and
hygienic safety testing of products intended for human
consumption

6. Products Concerned

Health monitoring and hygienic safety

7. Notification Under Another Act

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8. Main Content

The reform shall establish:

- a French Health Monitoring Institute with the task of monitoring the state of health of the population by relying on public or private watchdogs, detecting any new element likely to jeopardise it and alerting the public authorities.
- a French Agency for the Hygienic Safety of Health Products,



based on the model of the Medicines Agency. This establishment shall be responsible for guaranteeing the evaluation and testing of health products or would-be health products. This new establishment will put an end to the explosion of test structures based on product category (medicines, cosmetics, medical equipment, blood products, organs, tissues and human body cells, etc.), enable products which until now have had no status to be tested, and completely ensure the separation of production and testing functions.

- a French Agency for the Hygienic Safety of Food with the task of evaluating the hygienic risks of foodstuffs from the production of raw materials to their distribution to the end consumer. The conditions for using foodstuffs intended for animal fodder, veterinary medicines, suppressors, fertilising products and conditioners shall also within under the field of competence of the Agency to the extent that they can influence these risks.

The reform shall finally group together various provisions regarding different health products, whether these concern medical equipment, blood products, biological products or related therapeutic products which will eventually be granted status.

9. Brief Statement of Grounds

In the space of a few years, "hygienic safety" has become a new task of the State of vital importance in the same way as national or international security. This major development is associated with the outbreak of several crises which have beset our country in the last fifteen years.

Although the latter cover very different situations, their emergence has always been associated with confusion between, on the one hand, functions of risk evaluation, scientific and non-scientific identification of risk and exposure to risk and, on the other hand, functions of risk management which take into account the results of this evaluation and the interests at stake in determining political choices regarding the appropriate tests and regulatory measures.

The reform shall use the current competencies and structures of the health authorities and be based on the legislation in force in order to increase and improve their performance.

10. Reference Documents - Basic Texts

List of reference texts (cf. annex C)

11. Invocation of the Emergency Procedure

No



12. Grounds for the Emergency

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13. Confidentiality

No

14. Fiscal measures

No

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NNNN