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Legislation

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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COUNCIL

COUNCIL DECISION

of 18 April 1983

on the conclusion of the Agreement between the European Economic Community and the Swiss Confederation on a concerted action project in the field of cellular ageing

(83/224/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Decision 82/616/EEC of 17 August 1982 adopting a sectoral research and development programme of the European Economic Community in the field of medical and public health research – concerted action – (1982 to 1986) [1], and in particular Article 7 (1) thereof,

Having regard to the draft Decision submitted by the Commission,

Whereas, pursuant to Article 7 (2) of Decision 82/616/EEC, the Commission has negotiated an Agreement with the Swiss Confederation with a view to associating it partly with this programme; whereas it is necessary to approve that Agreement,

HAS DECIDED AS FOLLOWS:

Article 1

The Agreement concluded between the European Economic Community and the Swiss Confederation on a concerted action project in the field of cellular ageing is hereby approved on behalf of the Community.

The text of the Agreement is attached to this Decision.

Article 2

The President of the Council is hereby authorized to designate the persons empowered to sign the Agreement in order to bind the Community.

Done at Luxembourg, 18 April 1983.

For the Council

The President

I. KIECHLE

[1] OJ No L 248, 24. 8. 1982, p. 12.

AGREEMENT

between the European Economic Community and the Swiss Confederation on a concerted action project in the field of cellular ageing

THE EUROPEAN ECONOMIC COMMUNITY, hereinafter referred to as 'the Community';

and

THE SWISS CONFEDERATION,

Whereas a European concerted-action research project in the field of cellular ageing is likely to contribute effectively to the attainment of an optimum level of individual and public health;

Whereas, by its Decision of 17 August 1982, the Council of the European Communities adopted a sectoral research and development programme in the field of medical and public health research – concerted action – (1982 to 1986); which includes a concerted action project in the field of cellular ageing;

Whereas the Member States of the Community and the Swiss Confederation, hereinafter referred to as 'the States', intend, pursuant to the rules and procedures applicable to their national programmes, to carry out all or part of the research described in Annex A and are prepared to integrate such research within a framework of coordination which they consider will be of mutual benefit;

Whereas the estimated cost of the research described in Annex A to be conducted by the States amounts to 25 million ECU,

HAVE AGREED AS FOLLOWS:

Article 1

The Community and the Swiss Confederation, hereinafter referred to as 'the Contracting Parties', shall participate for a period from 1 January 1983 to 31 December 1986 in a concerted action project in the field of cellular ageing.

This project shall consist in the coordination of the Community's concerted action programme with that of the Swiss Confederation.

The research covered by this Agreement is described in Annex A.

The States shall remain entirely responsible for the research conducted by their national institutes or bodies.

Article 2

The Commission of the European Communities, hereinafter referred to as 'the Commission', shall be responsible for the coordination activities.

It shall be assisted in the execution of this task by a project leader.

Article 3

In order to facilitate the implementation of the project, the General Concerted Action Committee and the relevant Concerted Action Committee set up by the Decision of the Council of the European Communities of 17 August 1982 shall be enlarged to include the Swiss Confederation for the purpose of all activities arising from the concerted action project covered by this Agreement.

The terms of reference of these enlarged committees are defined in Annex B.

The secretarial services for these enlarged committees shall be provided by the Commission.

Article 4

The estimated financial contribution of the Contracting Parties to the coordination costs for the period referred to in Article 1 shall be:

— 600 000 ECU from the Community,

— 56 000 ECU from the Swiss Confederation.

The ECU is defined in the Financial Regulation applicable to the general budget of the European Communities and in the financial provisions adopted pursuant to that Regulation.

The rules governing the financing of the Agreement are set out in Annex C.

Article 5

The project shall be evaluated at the end of the third year.

As a result of this evaluation the Commission may, after consulting the enlarged General Committee, submit a proposal for revision of the project in accordance with the appropriate procedures.

Article 6

The States and the Commission shall periodically exchange all relevant information concerning the execution of the research covered by this Agreement. The States shall provide the Commission with all the information necessary for coordination purposes. They shall also endeavour to provide the Commission with information on similar research planned or carried out by bodies which are not under their authority. Any information will be treated as confidential if the State which supplies it so requests.

On completion of the programme, the Commission, in agreement with the enlarged General Committee, shall send to the States a consolidated report on the implementation and results of the programme, particularly so that the results obtained may be accessible as rapidly as possible to the enterprises, institutions and other parties concerned, especially in the social area.

Article 7

1. This Agreement shall enter into force on the day of its signature.

2. For a period of 12 months following its entry into force, this Agreement shall be open for accession by other European States which took part in the ministerial conference held in Brussels on 22 and 23 November 1971. The instruments of accession shall be deposited with the General Secretariat of the Council of the European Communities.

A State which accedes to this Agreement shall become a Contracting Party, within the meaning of Article 1, on the date on which the instrument of accession is deposited, and the references to 'the Swiss Confederation' which appear in this Agreement shall be construed as references to the acceding State also. Each acceding State shall contribute to the coordination costs under the conditions set out in Article 4 in reference to the Swiss Confederation.

3. The Secretary-General of the Council of the European Communities shall inform each of the Contracting Parties of the depositing of the instruments of accession referred to in paragraph 2.

Article 8

This Agreement shall apply, on the one hand, to the territories in which the Treaty establishing the European Economic Community is applied, under the conditions laid down in that Treaty, and, on the other hand, to the territory of the Swiss Confederation.

Article 9

This Agreement, drawn up in a single original in the Danish, Dutch, English, French, German, Greek and Italian languages, each text being equally authentic, shall be deposited in the archives of the General Secretariat of the Council of the European Communities, which shall transmit a certified copy to each of the Contracting Parties.

ANNEX A

RESEARCH COVERED BY THE AGREEMENT

1. *Cellular basis of liver- and brain-ageing:* biophysical and biochemical studies at the organic, cellular and sub-cellular level of progressive age-related functional alterations, including studies of senile dementia.

2. *The immune system during ageing:* study of age-induced changes in the immune system in animals and, to a lesser extent, in man, with particular emphasis on immunodeficiencies, possible forms of therapy and the origin of arthritic diseases.

3. *Ageing of the crystalline lens:* physiological, morphological and biochemical studies of age-related functional deterioration leading to senile cataracts in human and animal tissue.

ANNEX B

TERMS OF REFERENCE OF THE ENLARGED COMMITTEES

I. The enlarged General Concerted Action Committee

1. The General Committee shall:

   — contribute to the best possible implementation of the programme by giving its opinion on all its aspects,

   — endeavour to integrate those parts of national research activities covered by the Agreement into a process of coordination between the Contracting Parties,

   — within the programme as defined in Annex A to the Agreement, coordinate the activities, duration, and possibly, early termination of the projects forming the research areas of this programme, according to emerging needs or the results of periodical evaluations,

   — indicate guidelines to the enlarged Concerted Action Committee,

   — advise the Commission on allocation of funds for coordination purposes, supporting centralized facilities, meeting urgent needs in critical areas, and undertaking exploratory activities in view of the preparation of future programmes.

2. The reports and opinions of the enlarged General Committee shall be forwarded to the Contracting Parties. The Commission shall forward these opinions to the Committee for Scientific and Technical Research (CREST).

II. The enlarged Concerted Action Committee

1. The Committee shall:

   — assist the enlarged General Committee in its management tasks by ensuring the scientific and technical execution of all those projects assigned to it in accordance with its competence,

   — evaluate the results and draw conclusions as regards their application,

   — be responsible for the exchange of information referred to in the first paragraph of Article 6,

   — keep abreast of national research being done in the field of the projects and, more especially, of scientific and technical developments likely to affect their execution,

   — suggest guidelines to the project leader.

2. The Committee's reports and opinions shall be forwarded to the enlarged General Committee and to the Commission.

3. The project leader shall attend the meetings of the Committee but shall not have the right to vote.

ANNEX C

FINANCING RULES

Article 1

This Annex lays down the financial rules referred to in Article 4 of the Agreement on a concerted action project in the field of cellular ageing.

Article 2

At the beginning of each financial year, the Commission shall send to the Swiss Confederation a call for funds corresponding to its share of the annual coordination costs under the Agreement, calculated in proportion to the maximum amounts laid down in Article 4 of the Agreement.

This contribution shall be expressed both in ECU and in the currency of the Swiss Confederation, the value of the ECU being defined in the Financial Regulation applicable to the general budget of the European Communities and determined on the date of the call for funds.

The total contributions shall cover the travel and subsistence costs of the delegates to the Committee, in addition to the coordination costs proper.

The Swiss Confederation shall pay its annual contribution to the coordination costs under the Agreement at the beginning of each year, and by 31 March at the latest. Any delay in the payment of the annual contribution shall give rise to the payment of interest by the Swiss Confederation at a rate equal to the highest discount rate obtaining in the States on the due date. The rate shall be increased by 0,25 of a percentage point for each month of delay. The increased rate shall be applied to the entire period of delay. However, such interest shall be chargeable only if payment is effected more than three months after the issue of a call for funds by the Commission.

Article 3

The funds paid by the Swiss Confederation shall be credited to the concerted action project as budget receipts allocated to a heading in the statement of the revenue of the general budget of the European Communities (Commission section).

Article 4

The provisional timetable for the coordination costs referred to in Article 4 of the Agreement is annexed.

Article 5

The Financial Regulation applicable to the general budget of the European Communities shall apply to the management of the appropriations.

Article 6

At the end of each financial year, a statement of appropriations for the concerted action project shall be prepared and transmitted to the Swiss Confederation for information.

Annex to Annex C

PROVISIONAL TIMETABLE

for the coordination costs relating to the concerted action project in the field of cellular ageing

Budget Item 7367 'Medical research'

PROJECT: I.2.1

(ECU)

	1983		1984 and 1985		Total	
	AC	AP	AC	AP	AC	AP
I. Initial estimate of overall requirements:						
— Staff	—	—	—	—	—	—
— Administrative operating expenditure	50 000	50 000	50 000	50 000	200 000	200 000
— Contracts	100 000	100 000	100 000	100 000	400 000	400 000
Total	150 000	150 000	150 000	150 000	600 000	600 000
II. Revised estimate of expenditure taking into account additional requirements arising from the accession of the Swiss Confederation:						
— Staff	—	—	—	—	—	—
— Administrative operating expenditure	50 000 + 5 000	50 000 + 5 000	50 000 + 5 000	50 000 + 5 000	200 000 + 20 000	200 000 + 20 000
— Contracts	100 000 + 9 000	100 000 + 9 000	100 000 + 9 000	100 000 + 9 000	400 000 + 36 000	400 000 + 36 000
New total	150 000 + 14 000	150 000 + 14 000	150 000 + 14 000	150 000 + 14 000	600 000 + 56 000	600 000 + 56 000
III. Difference between I and II to be covered by the contribution from the Swiss Confederation	14 000	14 000	14 000	14 000	56 000	56 000

AC = Appropriation for commitments.
AP = Appropriation for payments.

COUNCIL DECISION

of 18 April 1983

on the conclusion of the Agreement between the European Economic Community and the Swiss Confederation extending and amending the Agreement on a concerted action project in the field of registration of congenital abnormalities (medical and public health research)

(83/225/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Decision 82/616/EEC of 17 August 1982 adopting a sectoral research and development programme of the European Economic Community in the field of medical and public health research – concerted action – (1982 to 1986) (1), and in particular Article 7 (1) thereof,

Having regard to Council Decision 79/696/EEC of 24 July 1979 on the conclusion of the Agreement between the European Economic Community and the Hellenic Republic on a concerted action project in the field of registration of congenital abnormalities (medical and public health research) (2),

Having regard to the draft Decision submitted by the Commission,

Whereas on 1 August 1980 the Swiss Confederation acceded to the aforementioned Agreement; whereas that Agreement was extended until 31 December 1981 (3);

Whereas, in accordance with Article 7 (2) of Decision 82/616/EEC, the Commission has negotiated an Agreement with the Swiss Confederation extending and amending the said Agreement; whereas it is necessary to approve that negotiated Agreement,

HAS DECIDED AS FOLLOWS:

Article 1

The Agreement between the European Economic Community and the Swiss Confederation extending and amending the Agreement on a concerted action project in the field of registration of congenital abnormalities (medical and public health research) is hereby approved on behalf of the Community.

The text of the Agreement is attached to this Decision.

Article 2

The President of the Council is hereby authorized to designate the persons empowered to sign the Agreement in order to bind the Community.

Done at Luxembourg, 18 April 1983.

For the Council

The President

I. KIECHLE

(1) OJ No L 248, 24. 8. 1982, p. 12.
(2) OJ No L 205, 13. 8. 1979, p. 27.
(3) OJ No L 113, 25. 4. 1981, p. 44.

AGREEMENT

between the European Economic Community and the Swiss Confederation extending and amending the Agreement on a concerted action project in the field of registration of congenital abnormalities (medical and public health research)

THE EUROPEAN ECONOMIC COMMUNITY,

and

THE SWISS CONFEDERATION,

hereinafter referred to as 'the Contracting Parties',

Whereas on 1 August 1980 the Swiss Confederation acceded to the Agreement on a concerted action project in the field of registration of congenital abnormalities (medical and public health research), hereinafter referred to as 'the Agreement', signed by the European Economic Community and the Hellenic Republic on 14 December 1979;

Whereas the Agreement expired on 31 December 1981;

Whereas, by its Decision of 17 August 1982, the Council of the European Communities adopted a sectoral research and development programme in the field of medical and public health research – concerted action – (1982 to 1986), which includes the continuation of the project relating to registration of congenital abnormalities;

Whereas it is in the common interest of the Contracting Parties to continue the research covered by the Agreement;

Whereas the renewal of the Agreement necessitates supplementary contributions from the Contracting Parties,

HAVE AGREED AS FOLLOWS:

Article 1

The Agreement shall be renewed for the period 1 January 1982 to 31 December 1986.

Article 2

The Agreement is hereby amended as follows:

1. Article 3 shall be replaced by the following:

   'Article 3

   In order to facilitate the execution of the project, the General Concerted Action Committee and the relevant Concerted Action Committee set up by the Decision of the Council of the European Communities of 17 August 1982 shall be enlarged to include the Swiss Confederation for the purposes of all activities arising from the concerted action project covered by this Agreement.

   The terms of reference of these enlarged Committees are set out in Annex B.

   The secretarial services for the enlarged Committees shall be provided by the Commission.'

2. Article 5 is hereby amended as follows:

   — the word 'Committee' in paragraph 1 shall be replaced by 'enlarged General Committee',

   — paragraph 2 shall be deleted,

   — paragraph 3 shall be replaced by the following:

   '2. On completion of the project, the Commission, in agreement with the enlarged General Committee, shall send to the States a consolidated report on the implementation and results of the project particularly so that the results obtained may be accessible as rapidly as possible to the enterprises, institutions and other parties concerned, especially in the social areas.'

3. The following text shall be added to Annex A:

   '2 *bis*. Improvement of intra-uterine diagnosis and studies on early foetal loss, death in early childhood and foetal growth disturbances.'

4. Annex B shall be replaced by Annex I to this Agreement.

5. Annex C shall be amended as follows:

   — point III shall be replaced by the following

   'III. The funds paid by the Swiss Confederation shall be credited to the concerted action project as budget receipts allocated to a chapter in the statement of revenue of the

budget of the European Communities (Commission section).'

— the provisional timetable annexed shall be replaced by Annex II to this Agreement.

Article 3

The estimated financial contribution from the Contracting Parties to the coordination costs for the period 1 January 1982 to 31 December 1986 shall be:

— 600 000 ECU from the European Economic Community,

— 55 000 ECU from the Swiss Confederation.

The ECU is defined in the Financial Regulation applicable to the general budget of the European Communities and in the financial provisions adopted pursuant to that Regulation.

Article 4

The project shall be evaluated before the end of the third year. In the light of this evaluation the Commission of the European Communities may, after consulting the enlarged General Committee, submit a proposal for revision of the project in accordance with the appropriate procedures.

Article 5

1. This Agreement shall enter into force on 1 January 1982.

2. It shall apply, on the one hand, to the territories in which the Treaty establishing the European Economic Community is applied, under the conditions laid down in that Treaty, and, on the other hand, to the territory of the Swiss Confederation.

Article 6

This Agreement, drawn up in a single original in the Danish, Dutch, English, French, German, Greek and Italian languages, each text being equally authentic, shall be deposited in the archives of the General Secretariat of the Council of the European Communities, which shall transmit a certified copy to each of the Contracting Parties.

ANNEX I

'ANNEX B

TERMS OF REFERENCE OF THE ENLARGED COMMITTEES

I. The enlarged General Concerted Action Committee

1. The General Committee shall:

   — contribute to the best possible implementation of the programme by giving its opinion on all its aspects,

   — endeavour to integrate those parts of national research activities covered by the Agreement into a process of coordination between the Contracting Parties,

   — coordinate, within the programme as defined in Annex A to the Agreement, the activities, duration and, possibly, early termination of the projects forming the research areas of this programme, according to emerging needs or results of periodical evaluations,

   — indicate guidelines for the enlarged Concerted Action Committee,

   — advise the Commission on allocation of funds for coordination purposes, supporting centralized facilities, meeting urgent needs in critical areas, and undertaking exploratory activities with a view to the preparation of future programmes.

2. The reports and opinions of the enlarged General Committee shall be forwarded to the Contracting Parties. The Commission shall forward these opinions to the Committee for Scientific and Technical Research (CREST).

II. The enlarged Concerted Action Committee

1. The Committee shall:

   — assist the enlarged General Committee in its management tasks by ensuring the scientific and technical execution of all those projects allocated to it in accordance with its competence,

   — evaluate the results and draw conclusions as regards their application,

   — be responsible for the exchange of information referred to in the first paragraph of Article 5,

   — keep abreast of national research being done in the field of the projects and, more especially, of scientific and technical developments likely to affect their execution,

   — suggest guidelines to the project leaders.

2. The Committee's reports and opinions shall be forwarded to the enlarged General Committee and to the Commission.

3. The project leaders shall attend the meetings of the Committee but shall not have the right to vote.'

ANNEX II

PROVISIONAL TIMETABLE

for the coordination costs relating to the concerted action project in the field of registration of congenital abnormalities

Budget Item 7367 'Medical research'

PROJECT: I.1.4

(ECU)

	1982		1983 to 1986		Total	
	AC	AP	Annual AC	Annual AP	AC	AP
I. Initial estimate of overall requirements:						
— Staff	—	—	—	—	—	—
— Administrative operating expenditure	20 000	20 000	20 000	20 000	100 000	100 000
— Contracts	100 000	100 000	100 000	100 000	500 000	500 000
Total	120 000	120 000	120 000	120 000	600 000	600 000
II. Revised estimate of expenditure taking into account additional requirements arising from the accession of the Swiss Confederation:						
— Staff	—	—	—	—	—	—
— Administrative operating expenditure	20 000 + 5 000	20 000 + 5 000	20 000 + 5 000	20 000 + 5 000	100 000 + 25 000	100 000 + 25 000
— Contracts	100 000 + 6 000	100 000 + 6 000	100 000 + 6 000	100 000 + 6 000	500 000 + 30 000	500 000 + 30 000
New total	120 000 + 11 000	120 000 + 11 000	120 000 + 11 000	120 000 + 11 000	600 000 + 55 000	600 000 + 55 000
III. Difference between I and II to be covered by contributions from the Swiss Confederation	11 000	11 000	11 000	11 000	55 000	55 000
IV. Total expenditure 1979 to 1981	—	—	—	—	352 000	352 000

AC = Appropriation for commitments.
AP = Appropriation for payments.

DECISION OF THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES OF THE EUROPEAN COAL AND STEEL COMMUNITY, MEETING WITHIN THE COUNCIL

of 18 April 1983

establishing ceilings and Community supervision for imports of certain goods originating in Yugoslavia (1983)

(83/226/ECSC)

THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES OF THE EUROPEAN COAL AND STEEL COMMUNITY, MEETING WITHIN THE COUNCIL,

In agreement with the Commission,

HAVE DECIDED AS FOLLOWS:

Article 1

1. Imports of certain products originating in Yugoslavia and indicated in Article 3 of the Agreement between the Member States of the European Coal and Steel Community and the European Coal and Steel Community, of the one part, and the Socialist Federal Republic of Yugoslavia, of the other part [1], shall be subject to annual ceilings and to Community supervision from 1 April to 31 December 1983. For 1983 the ceilings are to be applied *pro rata temporis*.

The description of the goods referred to in the preceding subparagraph, their tariff headings and statistical numbers and the levels of the indicative ceilings are given in the Annex to this Decision.

2. Amounts shall be set off against the ceilings as and when the goods are entered with customs authorities for free circulation and accompanied by a movement certificate conforming to the rules contained in Protocol 3 to the Cooperation Agreement between the European Economic Community and the Socialist Federal Republic of Yugoslavia [2].

Goods shall be set off against the ceiling only if the movement certificate has been submitted before the date on which customs duties are reimposed.

The reaching of a ceiling shall be determined at Community level on the basis of imports set off against it in the manner defined in the preceding subparagraphs.

The Member States shall periodically inform the Commission of imports effected in accordance with the above rules; such information shall be supplied under the conditions laid down in paragraph 4.

3. As soon as the ceilings are reached at Community level, Member States may at any time, at the request of any one of them or of the Commission, and in respect of the whole of the Community, reintroduce the levying of the customs duties applicable to third countries.

In the case of such a reimposition, Greece shall reintroduce the levying of the customs duties which it applies to third countries at the date in question.

Within the framework of the foregoing provisions, the Commission shall coordinate the procedures for reintroducing the customs duties applicable to third countries, in particular by notifying the date common to the whole of the Community and directly applicable in each Member State. This notification shall be published in the *Official Journal of the European Communities*.

4. Member States shall forward to the Commission, not later than the 15th day of each month, statements of the amounts set off during the preceding month. They shall, if the Commission so requests, make up such statements for periods of 10 days and forward them within five clear days of expiry of the preceding 10-day period.

Article 2

From 1 April to 31 December 1983 imports of the goods originating in Yugoslavia referred to in the Annex for which the ceiling level is not specified shall be subject to Community supervision.

Member States shall forward to the Commission, not later than the 15th day of each month, statements of imports of the products in question effected during the preceding month; to this end, only products submitted to the customs authorities under cover of an entry for free circulation and accompanied by a movement certificate conforming to the rules contained in Protocol 3, indicated in Article 1 (2), shall be taken into consideration.

(1) OJ No L 41, 14. 2. 1983, p. 113.
(2) OJ No L 41, 14. 2. 1983, p. 2.

They shall, if the Commission so requests, make up import statements for periods of 10 days and forward them within five clear days of expiry of the preceding 10-day period.

Article 3

Member States and the Commission shall cooperate closely to ensure that this Decision is complied with.

Article 4

Member States shall take all measures necessary to implement this Decision.

Done at Luxembourg, 18 April 1983.

The President

I. KIECHLE

ANNEX

Order No	CCT heading No	Description	NIMEXE code	Level of ceiling (tonnes)
1	2	3	4	5
ECSC 1	27.01	Coal; briquettes, ovoids and similar solid fuels manufactured from coal	27.01-all Nos	—
ECSC 2	27.02	Lignite, whether or not agglomerated	27.02-all Nos	—
ECSC 3	27.04	Coke and semi-coke of coal, of lignite or of peat, whether or not agglomerated; retort carbon:		—
		A. Coke and semi-coke of coal:		
		II. Other	27.04-19	
		B. Coke and semi-coke of lignite	27.04-30	
ECSC 4	73.01	Pig iron, cast iron and spiegeleisen, in pigs, blocks, lumps and similar forms:		14 983
		A. Spiegeleisen	73.01-10	
		B. Haematite pig iron and çast iron	73.01-21, 23, 25, 27	
		C. Phosphoric pig iron and cast iron	73.01-31, 35	
		D. Other pig iron and cast iron:		
		II. Other	73.01-49	
ECSC 5	73.02	Ferro-alloys:		
		A. Ferro-manganese:		
		I. Containing more than 2 % by weight of carbon (high carbon ferro-manganese)	73.02-01, 09	—
ECSC 6	73.03	Waste and scrap metal of iron or steel	73.03-all Nos	—
ECSC 7	73.05	Iron or steel powders; sponge iron or steel:		
		B. Sponge iron or steel	73.05-20	—
ECSC 8	73.06	Puddled bars and pilings; ingots, blocks, lumps and similar forms, of iron or steel	73.06-all Nos	—
ECSC 9	73.07	Blooms, billets, slabs and sheet bars (including tinplate bars), of iron or steel; pieces roughly shaped by forging, of iron or steel:		—
		A. Blooms and billets:		
		I. Rolled	73.07-12	
		B. Slabs and sheet bars (including tinplate bars):		
		I. Rolled	73.07-21, 24	
ECSC 10	73.08	Iron or steel coils for re-rolling	73.08-all Nos	21 751
ECSC 11	73.09	Universal plates of iron or steel	73.09-all Nos	—
ECSC 12	73.10	Bars and rods (including wire rod), of iron or steel, hot-rolled, forged, extruded, cold-formed or cold-finished (including precision-made); hollow mining drill steel:		
		A. Not further worked than hot-rolled or extruded	73.10-11, 13, 16, 18	

Order No	CCT heading No	Description	NIMEXE code	Level of ceiling (tonnes)
1	2	3	4	5
ECSC 12 *(cont'd)*	73.10 *(cont'd)*	D. Clad or surface-worked (for example, polished, coated):		14 332
		I. Not further worked than clad:		
		a) Hot-rolled or extruded	73.10-42	
ECSC 13	73.11	Angles, shapes and sections, of iron or steel, hot-rolled, forged, extruded, cold-formed or cold-finished; sheet piling of iron or steel, whether or not drilled, punched or made from assembled elements:		2 046
		A. Angles, shapes and sections:		
		I. Not further worked than hot-rolled or extruded	73.11-11, 12, 14, 16, 19	
		IV. Clad or surface-worked (for example, polished, coated):		
		a) not further worked than clad:		
		1. Hot-rolled or extruded	73.11-41	
		B. Sheet piling	73.11-50	
ECSC 14	73.12	Hoop and strip, of iron or steel, hot-rolled or cold-rolled:		4 228
		A. Not further worked than hot-rolled	73.12-11, 19	
		B. Not further worked than cold-rolled:		
		I. In coils for the manufacture of tinplate	73.12-21	
		C. Clad, coated or otherwise surface-treated:		
		III. Tinned:		
		a) Tinplate	73.12-51	
		V. Other (for example, copper-plated, artificially oxidized, lacquered, nickel-plated, varnished, clad, parkerized, printed):		
		a) Not further worked than clad:		
		1. Hot-rolled	73.12-71	
ECSC 15	73.13	Sheets and plates, of iron or steel, hot-rolled or cold-rolled:		26 214
		A. 'Electrical' sheets and plates	73.13-11, 16	
		B. Other sheets and plates:		
		I. Not further worked than hot-rolled	73.13-17, 19, 21, 23, 26, 32, 34, 36	
		II. Not further worked than cold-rolled, of a thickness of:		
		b) More than 1 mm but less than 3 mm	73.13-43, 45	
		c) 1 mm or less	73.13-47, 49	
		III. Not further worked than burnished, polished or glazed	73.13-50	
		IV. Clad, coated or otherwise surface-treated:		
		b) Tinned	73.13-64, 65	
		c) Zinc-coated or lead-coated	73.13-67, 68, 72, 74	
		d) Other (for example, copper-plated, artificially oxidized, lacquered, nickel-plated, varnished, clad, parkerized, printed)	73.13-76, 78, 79, 82, 84, 86, 87, 88, 89	
		V. Otherwise shaped or worked:		
		a) Cut into shapes other than rectangular shapes, but not further worked:		
		2. Other	73.13-92	

Order No	CCT heading No	Description	NIMEXE code	Level of ceiling (tonnes)
1	2	3	4	5
ECSC 16	73.15	Alloy steel and high carbon steel in the forms mentioned in heading Nos 73.06 to 73.14:		14 280
		A. High carbon steel:		
		I. Ingots, blooms, billets, slabs and sheet bars:		
		b) Other	73.61-20, 50	
		III. Coils for re-rolling	73.62-10	
		IV. Universal plates	73.62-30	
		V. Bars and rods (including wire rod) and hollow mining drill steel; angles, shapes and sections:		
		b) Not further worked than hot-rolled or extruded	73.63-21, 29	
		d) Clad or surface-worked (for example, polished, coated):		
		1. Not further worked than clad:		
		aa) Hot-rolled or extruded	73.63-72	
		VI. Hoop and strip:		
		a) Not further worked than hot-rolled	73.64-20	
		c) Clad, coated or otherwise surface-treated:		
		1. Not further worked than clad:		
		aa) Hot-rolled	73.64-72	
		VII. Sheets and plates:		
		a) Not further worked than hot-rolled	73.65-21, 23, 25	
		b) Not further worked than cold-rolled, of a thickness of:		
		2. Less than 3 mm	73.65-55	
		c) Polished, clad, coated or otherwise surface-treated	73.65-70	
		d) Otherwise shaped or worked:	73.65-81	
		1. Cut into shapes other than rectangular shapes, but not further worked		
		B. Alloy steel:		
		I. Ingots, blooms, billets, slabs and sheet bars:		
		b) Other:		
		1. Ingots:		
		bb) Other	73.71-23, 24, 29	
		2. Blooms, billets, slabs and sheet bars	73.71-53, 54, 55, 56, 59	
		III. Coils for re-rolling	73.72-11, 13, 19	
		IV. Universal plates	73.72-33, 39	
		V. Bars and rods (including wire rod) and hollow mining drill steel; angles, shapes and sections:		
		b) Not further worked than hot-rolled or extruded	73.73-23, 24, 25, 26, 29, 33, 34, 35, 36, 39	
		d) Clad or surface-worked (for example, polished, coated):		
		1. Not further worked than clad:		
		aa) Hot-rolled or extruded	73.73-72	

Order No	CCT heading No	Description	NIMEXE code	Level of ceiling (tonnes)
1	2	3	4	5
ECSC 16 *(cont'd)*	73.15 *(cont'd)*	B. VI. Hoop and strip:		
		a) Not further worked than hot-rolled	73.74-21, 23, 29	
		c) Clad, coated or otherwise surface-treated:		
		1. Not further worked than clad:		
		aa) Hot-rolled	73.74-72	
		VII. Sheets and plates:		
		a) 'Electrical' sheets and plates	73.75-11, 19	
		b) Other sheets and plates:		
		1. Not further worked than hot-rolled	73.75-23, 24, 29, 33, 34, 39, 43, 44, 49	
		2. Not further worked than cold-rolled, of a thickness of:		
		bb) less than 3 mm	73.75-63, 64, 69	
		3. Polished, clad, coated or otherwise surface-treated	73.75-73, 79	
		4. Otherwise shaped or worked:		
		aa) Cut into shapes other than rectangular shapes, but not further worked	73.75-83, 84, 89	
ECSC 17	73.16	Railway and tramway track construction material of iron or steel, the following: rails, check-rails, switch blades, crossings (or frogs), crossing pieces, point rods, rack rails, sleepers, fish-plates chairs, chair wedges, sole plates (base plates), rail clips, bedplates, ties and other material specialized for joining or fixing rails:		—
		A. Rails:		
		II. Other:	73.16-14, 16, 17	
		B. Check-rails	73.16-20	
		C. Sleepers	73.16-40	
		D. Fish-plates and sole plates:		
		I. Rolled	73.16-51	

DECISION OF THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES OF THE EUROPEAN COAL AND STEEL COMMUNITY, MEETING WITHIN THE COUNCIL

of 18 April 1983

laying down the arrangements applicable to trade between Greece and Yugoslavia in products covered by that Community

(83/227/ECSC)

THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES OF THE EUROPEAN COAL AND STEEL COMMUNITY, MEETING WITHIN THE COUNCIL,

Whereas the Member States have concluded among themselves the Treaty establishing the European Coal and Steel Community;

Whereas the Protocol to the Agreement between the Member States of the European Coal and Steel Community and the Socialist Federal Republic of Yugoslavia, hereinafter referred to respectively as 'the Protocol' and 'the Agreement', to take account of the accession of the Hellenic Republic to the Community, was signed on 1 April 1982;

Whereas, pending the entry into force of the Protocol, the Member States of the European Coal and Steel Community should, in the light of the provisions of the said Protocol, lay down autonomously the arrangements applicable to trade between Greece and Yugoslavia;

In agreement with the Commission,

HAVE DECIDED AS FOLLOWS:

Article 1

Until the entry into force of the Protocol, the arrangements applicable to trade between Greece and Yugoslavia shall be those resulting from the Annex to this Decision.

Article 2

Member States shall take the measures necessary to implement this Decision.

Done at Luxembourg, 18 April 1983.

The President

I. KIECHLE

ANNEX

SPECIFIC CONDITIONS OF APPLICATION OF THE AGREEMENT BETWEEN THE MEMBER STATES OF THE EUROPEAN COAL AND STEEL COMMUNITY AND THE SOCIALIST FEDERAL REPUBLIC OF YUGOSLAVIA CONSEQUENT UPON THE ACCESSION OF THE HELLENIC REPUBLIC

Article 1

1. For the products specified in the Annex, the volume of the annual ceilings applied by the Community to products originating in Yugoslavia, in accordance with Article 3 of the Agreement, shall be increased. The volume of the annual ceilings for 1983 for the products in question is laid down in the Annex.

2. Under the Community ceilings established for the products listed in Article 3 of the Agreement, the Hellenic Republic shall apply customs duties calculated in accordance with Article 2.

3. If, during the period of application of the transitional measures, customs duties applicable to third countries are reintroduced by the Community in respect of imports of products referred to in Article 3 of the Agreement, the Hellenic Republic shall reintroduce the customs duties applicable to third countries in respect of the same products on the date in question.

Article 2

For the products covered by the Agreement, the Hellenic Republic shall progressively abolish the customs duties applied on the import of products originating in Yugoslavia in accordance with the following timetable:

— on the date of this Decision's entry into force, each duty shall be reduced to 60 % of the basic duty,

— the three other reductions of 20 % each shall be made on:

  — 1 January 1984,
  — 1 January 1985,
  — 1 January 1986.

Article 3

The basic duty to which the successive reductions as provided for in Article 2 are to be applied shall, for each product, be the duty actually applied on 1 July 1980 by the Hellenic Republic in respect of Yugoslavia.

Article 4

1. The Hellenic Republic shall progressively abolish charges having equivalent effect to customs duties on products originating in Yugoslavia in accordance with the following timetable:

— on the date of this Decision's entry into force, each charge shall be reduced to 60 % of the basic rate,

— the three other reductions of 20 % each shall be made on:

  — 1 January 1984,
  — 1 January 1985,
  — 1 January 1986.

2. The basic rate to which the successive reductions as provided for in paragraph 1 are to be applied shall, for each product, be the rate applied by the Hellenic Republic on 31 December 1980 in respect of the Community of Nine.

3. Any charge having equivalent effect to a customs duty on imports, introduced as from 1 January 1979, in trade between Greece and Yugoslavia shall be abolished.

Article 5

If the Hellenic Republic suspends or reduces customs duties or charges having equivalent effect on products imported from the Community of Nine more quickly than determined by the timetable set out in Articles 2 and 4, the Hellenic Republic shall also suspend or reduce to the same level those duties or charges having equivalent effect on products originating in Yugoslavia.

Article 6

1. Import deposits and cash payments in force in Greece on 31 December 1980 with regard to products originating in Yugoslavia shall be eliminated in accordance with the following timetable:

— from the date of this Decision's entry into force: 75 %,

— 1 January 1984: 25 %.

2. If in relation to the Community of Nine the Hellenic Republic reduces the rate of import deposits or cash payments more quickly than determined by the timetable set out in paragraph 1, the Hellenic Republic shall make the same reduction with regard to imports originating in Yugoslavia.

Annex

List referred to in Article 1

Brussels Nomenclature heading No (CCCN)	Description	Ceiling (tonnes)
73.10	Bars and rods (including wire rod), of iron or steel, hot-rolled, forged, extruded, cold-formed or cold-finished (including precision-made); hollow mining drill steel: A. Not further worked than hot-rolled or extruded D. Clad or surface-worked (for example, polished, coated): I. Not further worked than clad: a) Hot-rolled or extruded	19 110
73.11	Angles, shapes and sections, or iron or steel, hot-rolled, forged, extruded, cold-formed or cold-finished; sheet piling of iron or steel, whether or not drilled, punched or made from assembled elements: A. Angles, shapes and sections: I. Not further worked than hot-rolled or extruded IV. Clad or surface-worked (for example, polished, coated): a) Nor further worked than clad: 1. Hot-rolled or extruded B. Sheet piling	2 728
73.12	Hoop and strip, of iron or steel, hot-rolled or cold-rolled: A. Not further worked than hot-rolled B. Not further worked than cold-rolled: I. In coils for the manufacture of tinplate (a) C. Clad, coated or otherwise surface-treated: III. Tinned: a) Tinplate V. Other (for example, copper-plated, artificially oxidized, lacquered, nickel-plated, varnished, clad, parkerized, printed): a) Nor further worked than clad: 1. Hot-rolled	5 638
73.13	Sheets and plates, of iron or steel, hot-rolled or cold-rolled: A. 'Electrical' sheets and plates B. Other sheets and plates: I. Not further worked than hot-rolled II. Not further worked than cold-rolled, of a thickness of: b) More than 1 mm but less than 3 mm c) 1 mm or less III. Not further worked than burnished, polished or glazed IV. Clad, coated or otherwise surface-treated: b) Tinned c) Zinc-coated or lead-coated d) Other (for example, copper-plated, artificially oxidized, lacquered, nickel-plated, varnished, clad, parkerized, printed)	34 953

(a) Entry under this subheading is subject to conditions to be determined by the competent authorities.

Brussels Nomenclature heading No (CCCN)	Description	Ceiling (tonnes)
73.13 *(cont'd)*	V. Otherwise shaped or worked: a) Cut into shapes other than rectangular shapes, but not further worked: 2. Other	
73.15	Alloy steel and high carbon steel in the forms mentioned in heading Nos 73.06 to 73.14: A. High carbon steel: I. Ingots, blooms, billets, slabs and sheet bars: b) Other: 1. Ingots 2. Blooms, billets, slabs and sheet bars III. Coils for re-rolling IV. Universal plates V. Bars and rods (including wire rod) and hollow mining drill steel; angles, shapes and sections: b) Not further worked than hot-rolled or extruded d) Clad or surface-worked (for example, polished, coated): 1. Not further worked than clad: aa) Hot-rolled or extruded VI. Hoop and strip: a) Not further worked than hot-rolled c) Clad, coated or otherwise surface-treated: 1. Not further worked than clad: aa) Hot-rolled VII. Sheets and plates: a) Not further worked than hot-rolled b) Not further worked than cold-rolled, of a thickness of: 2. Less than 3 mm c) Polished, clad, coated or otherwise surface-treated d) Otherwise shaped or worked: 1. Cut into shapes other than rectangular shapes, but not further worked B. Alloy steel: I. Ingots, blooms, billets, slabs and sheet bars: b) Other: 1. Ingots: bb) Other 2. Blooms, billets, slabs and sheet bars III. Coils for re-rolling IV. Universal plates V. Bars and rods (including wire rod) and hollow mining drill steel; angles, shapes and sections: b) Not further worked than hot-rolled or extruded d) Clad or surface-worked (for example, polished, coated): 1. Not further worked than clad: aa) Hot-rolled or extruded	19 041

Brussels Nomenclature heading No (CCCN)	Description	Ceiling (tonnes)
73.15 *(cont'd)*	B. VI. Hoop and strip: a) Not further worked than hot-rolled c) Clad, coated or otherwise surface-treated: 1. Not further worked than clad: aa) Hot-rolled VII. Sheets and plates: a) 'Electrical' sheets and plates b) Other sheets and plates: 1. Not further worked than hot-rolled 2. Not further worked than cold-rolled, of a thickness of: bb) Less than 3 mm 3. Polished, clad, coated or otherwise surface-treated 4. Otherwise shaped or worked: aa) Cut into shapes other than rectangular shapes, but not further worked	

COUNCIL DIRECTIVE
of 18 April 1983
on the fixing of guidelines for the assessment of certain products used in animal nutrition

(83/228/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition (1), and in particular Article 7 thereof,

Having regard to the proposal from the Commission,

Whereas Directive 82/471/EEC provides that the products belonging to certain groups must be examined on the basis of a dossier forwarded officially to the Member States and the Commission;

Whereas such dossiers must make it possible to verify that the products in question comply with the general principles laid down in the Directive in respect of the inclusion of new products in the Annex;

Whereas it has been found necessary to provide for the dossiers to be compiled in accordance with common guidelines defining, for each principle, the scientific data which make it possible to identify and characterize the products concerned and the studies necessary in order to evaluate their nutritional properties and biological effects; whereas these guidelines must be applicable on the date on which Directive 82/471/EEC itself enters into force;

Whereas the guidelines are intended primarily as a general guide; whereas, depending on the nature of the product or its conditions of use, the extent of the studies necessary in order to evaluate its properties or its effects may vary;

Whereas the guidelines have been drawn up on the basis of present scientific and technical knowledge and they may be adapted if necessary to any developments in this sphere,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Member States shall prescribe that the dossiers on the products listed in points 1.1 and 1.2 of the Annex to Directive 82/471/EEC are to be compiled in accordance with the guidelines set out in the Annex hereto.

Article 2

Member States shall bring into force the laws, regulations or administrative provisions necessary in order to comply with this Directive by 13 July 1984 at the latest. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Luxembourg, 18 April 1983.

For the Council

The President

I. KIECHLE

(1) OJ No L 213, 21. 7. 1982, p. 8.

ANNEX

GUIDELINES FOR THE ASSESSMENT OF CERTAIN PRODUCTS USED IN ANIMAL NUTRITION

General aspects

These 'guidelines' constitute a guide intended to establish dossiers on products listed in items 1.1 and 1.2 of the Annex to Directive 82/471/EEC, which have been obtained from culturing micro-organisms and which are likely to be admitted as a new source of proteins in animal nutrition. These dossiers should enable an assessment of such products based on the present state of knowledge and should ensure their compliance with the fundamental principles laid down for permitting their use, which are the subject of Article 6 (2) of the abovementioned Directive.

All the studies outlined in this document may be required and, if necessary, additional information may be requested. As a general rule, all the information necessary to establish the identity of the micro-organism and the composition of the culture medium, and also the manufacturing process, characteristics, presentation, conditions of use, methods of determination and nutritional properties of the product must be provided. The same applies to the information necessary to assess the tolerance of the product by the target species and the risks for man and the environment, which could result directly or indirectly from the use of the product. The toxicological studies required for this purpose will depend on the nature of the product, the animal species concerned and the metabolism of the product in laboratory animals.

The documentation to be provided should include detailed reports, presented in the order and with the numbering proposed in these guidelines and should be accompanied by a summary. The omission of any proposed studies should be justified. The publications quoted as references should be attached.

Observations

The term 'product', as used in these guidelines, refers to any proteinaceous product in the state in which it will be presented as feedingstuff or component of a feedingstuff.

Any modification in the manufacturing process or in the conditions of use of a product will require notification and, if necessary, additional documentation for a new assessment.

Presentation of studies

I. Micro-organism, culture medium and manufacturing process, characteristics of product, presentation and conditions of use, methods of determination

II. Studies on the nutritional properties of the product

III. Studies on the biological consequences of the use of the product in animal nutrition

IV. Other relevant studies

SECTION I

MICRO-ORGANISM CULTURE MEDIUM AND MANUFACTURING PROCESS, CHARACTERISTICS OF PRODUCT, PRESENTATION AND CONDITIONS OF USE, METHODS OF DETERMINATION

1. MICRO-ORGANISM

1.1. Classification, provenance, morphology, biological properties, any genetic manipulation.

1.2. Innocuity, possible survival outside the fermenter and any environmental consequences.

1.3. Constancy and purity of strains cultivated. Methods used to check these criteria.

2. CULTURE MEDIUM AND MANUFACTURING PROCESS

2.1. Composition of substrate, added substances, etc.

2.2. Manufacturing, dessication and purification processes. Devitalizing process for micro-organisms. Methods used to check the constancy of composition of the culture product and the detection of any chemical, physical and biological contamination during production.

2.3. Technical processes of preparation for use.

3. CHARACTERISTICS OF PRODUCT

3.1. Physical and physico-chemical properties: macro- and micro-morphology, particle size, density, specific weight, hygroscopicity, solubility, electrostatic properties, etc.

3.2. Chemical composition and characteristics.

3.2.1. Content of moisture, crude protein, crude fat, crude cellulose, crude ash, carbohydrates. Limits of variation of these contents.

3.2.2. Content of total ammonium, amide, nitrate and nitrite nitrogen, nucleic acids, protein. Qualitative and quantitative composition of total and free amino acids, and purine and pyrimidine bases.

3.2.3. Qualitative and quantitative composition of total lipids: fatty acids, non-saponifiable matter, lipid soluble pigments, phospholipids.

3.2.4. Composition of the carbohydrate fraction.

3.2.5. Qualitative and quantitative composition of inorganic components.

3.2.6. Qualitative and quantitative composition of vitamins.

3.2.7. Qualitative and quantitative composition of the other constituents: additives, residues of substrate and solvents, other potentially harmful residues of the metabolism of the substrate, of the culture medium, of the manufacturing process.

3.3. Microbiological contamination of the product.

3.4. Behaviour and stability of the product, as such and when mixed with feedingstuffs in current use, during storage.

4. PRESENTATION AND CONDITIONS OF USE

4.1. Proposed names of marketing the product.

4.2. Proposed formulations for marketing the product.

4.3. Intended use of the product in animal nutrition. Intended concentrations in the complete feedingstuffs and in the intended quantities in the daily rations for the animal species concerned.

5. METHODS OF DETERMINATION

Qualitative and quantitative methods for determination of the product in complete and complementary feedingstuffs.

NB: Description of these methods should be accompanied by information as to specificity, sensitivity, limits of detection, margin of error, possible interferences by other substances. Samples of the product in its various proposed presentations should be available.

SECTION II

STUDIES ON THE NUTRITIONAL PROPERTIES OF THE PRODUCT

1. ASSESSMENT OF PROTEIN VALUE

1.1. Chemical, biochemical and microbiological studies.

1.2. Studies on laboratory animals, compared with reference proteins.

2. STUDIES ON TARGET SPECIES

The following studies should be performed on each target species in comparison with a control group receiving, under the same conditions of nutritional balance, a diet in current use containing equivalent amounts of protein nitrogen, for ruminants of total nitrogen.

2.1. Protein and energy supplementation value of the product in the rations under the proposed conditions of use at various physiological stages of the animals (e.g. growing period, pregnancy, laying).

2.2. Influence of the product under the proposed conditions of use on growth rate, feed conversion rate, morbidity, mortality.

2.3. Optimum nutritional levels of incorporation of the product in the rations.

2.4. Effect of the product under the proposed conditions of use on the technological, organoleptic or other qualities of edible products of animal origin.

3. EXPERIMENTAL CONDITIONS IN THE STUDIES ON TARGET SPECIES

Give a detailed description of the tests performed and provide the following data:

3.1. Species, breed, age and sex of the animals, identification procedure.

3.2. Number of test and control groups; number of animals in each group (the number should be large enough for statistical analysis using suitable statistical parameters).

3.3. Levels of incorporation of the product, qualitative and quantitative composition of the ration and its analysis.

3.4. Location of each experiment, physiological state and animal health conditions, rearing conditions (these should reflect those used in practice in the Community).

3.5. Exact duration of testing and date of the analyses performed.

3.6. Adverse effects which occurred during the experiment and time of their appearance.

SECTION III

STUDIES CONCERNING THE BIOLOGICAL CONSEQUENCES OF THE USE OF THE PRODUCT IN ANIMAL NUTRITION

The studies outlined in this section are intended to permit assessment of the safety in use of the product in the target species, and of the risks for man and the environment which could result directly or indirectly from this use. The toxicological studies required for this purpose will depend on the nature of the product, the animal species concerned and the metabolism of the product in laboratory animals.

1. STUDIES ON TARGET SPECIES

The following studies should be performed on each target species in comparison with a control group receiving, under the same conditions of nutritional balance, a diet in current use containing equivalent amounts of protein nitrogen, for ruminants of total nitrogen.

1.1. Maximum incorporation rates of the product in the daily ration without producing any adverse effect.

1.2. Possible effect of the product on fertility and reproduction, if appropriate.

1.3. Effects of ingestion of the product under the proposed conditions of use on micro-organisms of the flora of the alimentary tract and on colonization of pathogens in the alimentary tract.

1.4. Investigation under the proposed conditions of use of possible residues of the product (substrate, culture medium, solvents, contaminants) in edible products of animal origin.

1.5. Investigation under the proposed conditions of use of possible residues of the product (substrate, culture medium, solvents, contaminants) in excreta.

2. STUDIES ON LABORATORY ANIMALS

2.1. **Metabolism**

Fate of the product in the animal: absorption, accumulation, biotransformation, elimination.

2.2. **Mutagenicity**

Investigations of potential mutagenicity due to contaminants (in particular mycotoxins and bacteria) or residues of the product (substrate, culture medium, solvents) including *in vitro* screening tests using metabolic activation systems.

2.3. **Toxicological studies**

The following studies should be performed in comparison with control groups receiving, under the same conditions of nutritional balance, a diet in current use containing equivalent amounts of protein nitrogen. Toxic effects should be investigated to elucidate their cause and mechanisms and to ascertain that they do not result from nutritional imbalance or from an overdosage of the product in the diet.

2.3.1. *Subchronic toxicity (at least 90 days)*

In general, these studies should be carried out on two animal species, one of which being a rodent. The product should be administered in the daily ration in at least two levels of incorporation. These should be chosen so as to determine, if possible, a no-effect level and a level showing some adverse effect. The animal groups should contain an adequate number of subjects of each sex. A control group should always be included.

All relevant biological data should be recorded at appropriate intervals, particularly data on growth rate, feed consumption, haematology, urine analysis, biochemical parameters, mortality, organ

weights, gross pathology and histopathology of major organs and tissues. The results should be presented in detail and, as far as possible, should include statistical assessment.

2.3.2. *Chronic toxicity*

In general, chronic toxicity studies should be carried out on two animal species, one of which being a rodent. The product should be admininstered in the daily ration in at least two levels of incorporation. Experiments should extend for a minimum of two years in the rat or 80 weeks in mice. The animal groups should contain an adequate number of subjects of each sex. A control group should always be included.

The biological examinations mentioned under point 2.3.1 should be carried out preferably on a small satellite group of animals (a group separated from and dependent upon the main group) at appropriate intervals throughout the experiment and on the surviving animals at the end of the experiment.

2.3.3. *Carcinogenicity*

For assessing carcinogenicity, particular attention should be paid to the time of appearance, the histological types of any observed tumours and their incidence. Any effect on the incidence of tumours and/or the incidence or progress of diseases should be assessed by reference to control groups, as indicated in paragraph 2.3. The results should be presented in detail and, as far as possible, should include statistical assessment.

2.4. **Other studies**

Reproduction studies should extend over at least two filial generations and may be combined with embryotoxicity including teratogenicity studies. Particular attention should be paid to fertility, fecundity and observation on post-natal development of litters. Any other method that is scientifically justifiable and likely to produce measurable results (e.g. relay toxicity) may be provided.

2.5. **Experimental conditions in the studies on laboratory animals**

Give detailed description of the tests performed and provide the following data:

2.5.1. Species, breed, strain and sex of animals.

2.5.2. Number of test and control groups, number of animals in each group (the number should be large enough for statistical analysis using suitable statistical parameters).

2.5.3. Levels of incorporation of the product, qualitative and quantitative composition of the ration and its analysis.

2.5.4. General rearing conditions throughout the period of testing.

2.5.5. Exact duration of testing and date of examinations performed.

2.5.6. Rate and timing of deaths for the various test groups.

2.5.7. Clinical symptoms and pathological alterations which occurred during the experiment and time of their appearance.

3. STUDIES CONCERNING THE ENVIRONMENT

Depending on the nature of possible residues of the product (substrate, culture medium, solvents, contaminants) in excreta of target species, data on the fate of these residues in manure, soil and water and also their effects on soil biology, plant growth and aquatic life may be required.

SECTION IV

OTHER RELEVANT STUDIES

Depending on the nature and the conditions of use of the product, data on allergic effects, on irritation of the skin and mucus membranes of the eye, respiratory or digestive tract may be required to assess possible risks in handling the product and to prevent them.

THE COMMUNITY LEGAL ORDER

Jean-Victor LOUIS

The European Communities are not simply a forum of discussion and negotiation between States. Their institutional structure, far more complex and original than that of traditional international organizations, has given birth to a vast quantity of legislation, most of which can be relied upon directly before national courts. The Court of Justice of the three Communities is faced with a workload increasing year by year in its efforts both to clarify the interpretation of Community law for the benefit of national courts and to resolve disputes between the institutions and individuals or Member States. In short, the Communities constitute a unique legal order with a highly complex structure, which penetrates further every day into economic and social reality in the Member States, yet still remains largely unrecognized.

This work on 'The Community legal order' from the pen of Professor Jean-Victor Louis of the Free University of Brussels, published by the Commission of the European Communities, is designed to enable the reader, with very little expenditure of time, to familiarize himself with the main characteristics of this system. It is written in a form easily understood by the layman, but its precise information and critical approach make it equally suitable for use by lawyers as a work of reference.

Jean-Victor Louis — Born 10 January 1938 — Agrégé in international law, Brussels University (ULB), 1969 — Lecturer in Community law, ULB — Former Director and Research Director, European Studies Department, ULB — Director of the Cahiers de Droit Européen — Head of the Legal Department, Banque Nationale de Belgique — Author of 'Les règlements de la Communauté économique européenne' and, with others, of 'Le droit de la Communauté économique européenne', ed. Jacques Mégret (nine volumes published).

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