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I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 2033/94

of 9 August 1994

establishing unit values for the determination of the customs value of certain perishable goods

THE COMMISSION OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code ⁽¹⁾,

Having regard to Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code ⁽²⁾, as last amended by Regulation (EC) No 1500/94 ⁽³⁾, and in particular Article 173 (1) thereof,

Whereas Articles 173 to 177 of Regulation (EEC) No 2454/93 provide that the Commission shall periodically establish unit values for the products referred to in the classification in Annex 26 to that Regulation;

Whereas the result of applying the rules and criteria laid down in the abovementioned Articles to the elements

communicated to the Commission in accordance with Article 173 (2) of Regulation (EEC) No 2454/93 is that unit values set out in the Annex to this Regulation should be established in regard to the products in question,

HAS ADOPTED THIS REGULATION:

Article 1

The unit values provided for in Article 173 (1) of Regulation (EEC) No 2454/93 are hereby established as set out in the table in the Annex hereto.

Article 2

This Regulation shall enter into force on 12 August 1994.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 9 August 1994.

For the Commission

Christiane SCRIVENER

Member of the Commission

⁽¹⁾ OJ No L 302, 19. 10. 1992, p. 1.

⁽²⁾ OJ No L 253, 11. 10. 1993, p. 1.

⁽³⁾ OJ No L 162, 30. 6. 1994, p. 1.

ANNEX

Code	CN code	Description	Amount of unit values per 100 kg net									
			ECU	Bfrs/Lfrs	Dkr	DM	FF	Dr	£ Irl	Lit	Fl	£
1.10	0701 90 51 0701 90 59	New potatoes	31,55	1 247	238,43	60,58	207,43	9 150	25,01	60 478	68,06	24,80
1.20	0702 00 10 0702 00 90	Tomatoes	40,82	1 614	307,41	78,42	268,10	11 854	32,57	77 776	87,96	32,19
1.30	0703 10 19	Onions (other than seed)	28,70	1 134	216,91	55,11	188,70	8 324	22,75	55 018	61,91	22,56
1.40	0703 20 00	Garlic	70,67	2 794	532,22	135,77	464,16	20 524	56,40	134 652	152,29	55,73
1.50	ex 0703 90 00	Leeks	55,11	2 191	416,83	106,38	362,51	15 522	43,90	105 358	119,58	42,20
1.60	ex 0704 10 10 ex 0704 10 90	Cauliflowers	57,81	2 331	438,81	113,34	385,48	15 133	43,14	104 614	127,38	45,06
1.70	0704 20 00	Brussels sprouts	53,71	2 172	405,33	104,22	354,64	14 950	41,74	101 870	116,85	40,02
1.80	0704 90 10	White cabbages and red cabbages	17,14	681	129,98	33,09	113,00	4 877	13,79	31 888	37,18	13,32
1.90	ex 0704 90 90	Sprouting broccoli or calabrese (<i>Brassica oleracea</i> var. <i>italica</i>)	79,26	3 206	598,09	153,78	523,30	22 060	61,59	150 316	172,41	59,05
1.100	ex 0704 90 90	Chinese cabbage	36,78	1 463	279,14	71,12	243,78	10 454	29,10	68 223	79,83	28,31
1.110	0705 11 10 0705 11 90	Cabbage lettuce (head lettuce)	40,96	1 632	310,06	79,27	269,67	11 511	32,39	78 153	88,99	31,08
1.120	ex 0705 29 00	Endives	21,82	877	162,70	42,58	143,89	5 690	17,51	39 262	47,92	17,72
1.130	ex 0706 10 00	Carrots	16,90	673	128,33	32,72	111,98	4 793	13,36	31 281	36,73	12,98
1.140	ex 0706 90 90	Radishes	60,46	2 405	458,53	116,76	398,62	17 204	48,65	112 485	131,17	47,01
1.150	0707 00 11 0707 00 19	Cucumbers	55,21	2 193	417,12	106,57	364,08	15 879	43,67	103 026	119,50	42,86
1.160	0708 10 10 0708 10 90	Peas (<i>Pisum sativum</i>)	298,91	11 814	2 258,77	573,94	1 965,04	86 683	236,94	572 927	644,79	235,03
1.170		Beans :										
1.170.1	0708 20 10 0708 20 90	Beans (<i>Vigna</i> spp., <i>Phaseolus</i> spp.)	273,15	10 802	2 057,05	524,78	1 794,00	79 325	218,00	520 430	588,63	215,43
1.170.2	0708 20 10 0708 20 90	Beans (<i>Phaseolus</i> ssp., <i>vulgaris</i> var. <i>Compressus Savi</i>)	91,26	3 616	687,78	174,91	600,77	26 404	72,93	174 000	196,24	72,04
1.180	ex 0708 90 00	Broad beans	92,83	3 894	734,40	189,09	645,42	21 793	71,04	142 837	212,96	66,61
1.190	0709 10 00	Globe artichokes	61,64	2 453	467,78	119,18	408,52	17 518	48,77	114 325	133,77	47,45
1.200		Asparagus :										
1.200.1	ex 0709 20 00	— green	418,57	16 543	3 162,93	803,68	2 751,63	121 382	331,78	802 263	902,89	329,11
1.200.2	ex 0709 20 00	— other	217,11	8 646	1 639,96	420,00	1 429,46	63 062	171,19	406 332	470,91	167,19
1.210	0709 30 00	Aubergines (egg-plants)	95,92	3 814	724,88	185,31	635,57	27 371	75,84	177 278	208,01	74,00
1.220	ex 0709 40 00	Ribbed celery (<i>Apium graveolens</i> var. <i>dulce</i>)	80,83	3 211	610,71	156,02	533,05	23 248	63,94	150 841	174,96	62,75
1.230	0709 51 30	Chantarelles	979,35	38 730	7 375,30	1 881,55	6 432,17	284 413	781,61	1 865 939	2 110,49	772,40
1.240	0709 60 10	Sweet peppers	133,65	5 282	1 009,97	256,63	878,64	38 759	105,94	256 175	288,30	105,09
1.250	0709 90 50	Fennel	73,55	2 966	558,22	144,18	490,38	19 251	54,88	133 083	162,05	57,33
1.260	0709 90 70	Courgettes	29,03	1 156	220,33	56,18	192,26	8 230	22,94	53 707	63,06	22,28
1.270	ex 0714 20 10	Sweet potatoes, whole, fresh (intended for human consumption)	47,43	1 876	357,25	91,14	311,57	13 776	37,86	90 384	102,23	37,41
2.10	ex 0802 40 00	Chestnuts (<i>Castanea</i> spp.), fresh	83,78	3 378	639,04	164,08	560,82	21 691	62,54	145 547	184,60	66,87
2.20												
2.30	ex 0804 30 00	Pineapples, fresh	55,23	2 183	417,40	106,06	363,12	16 018	43,78	105 872	119,15	43,43
2.40	ex 0804 40 10 ex 0804 40 90	Avocados, fresh	86,10	3 403	650,65	165,32	566,04	24 969	68,25	165 034	185,73	67,70

Code	CN code	Description	Amount of unit values per 100 kg net									
			ECU	Bfrs/Lfrs	Dkr	DM	FF	Dr	£ Irl	Lit	Fl	£
2.50	ex 0804 50 00	Guavas and mangoes, fresh	111,75	4 416	844,49	214,58	734,68	32 408	88,58	214 202	241,07	87,87
2.60		Sweet oranges, fresh :										
2.60.1	0805 10 11 0805 10 21 0805 10 31 0805 10 41	— Sanguines and semi-sanguines	41,70	1 648	315,13	80,07	274,15	12 093	33,05	79 933	89,95	32,79
2.60.2	0805 10 15 0805 10 25 0805 10 35 0805 10 45	— Navels, Navelines, Navelates, Salustianas, Vernas, Valencia lates, Maltese, Shamoutis, Ovalis, Trovita and Hamlins	48,31	1 909	365,09	92,76	317,61	14 010	38,29	92 604	104,21	37,98
2.60.3	0805 10 19 0805 10 29 0805 10 39 0805 10 49	— Others	36,41	1 439	275,20	69,92	239,41	10 561	28,86	69 804	78,56	28,63
2.70		Mandarins (including tangerines and satsumas), fresh ; clementines, wilkings and similar citrus hybrids, fresh :										
2.70.1	ex 0805 20 10	— Clementines	41,07	1 623	310,41	78,87	270,05	11 912	32,56	78 735	88,61	32,29
2.70.2	ex 0805 20 30	— Monreales and Satsumas	44,91	1 776	338,25	86,29	295,00	13 044	35,84	85 578	96,79	35,42
2.70.3	ex 0805 20 50	— Mandarins and wilkings	50,74	2 005	383,46	97,43	333,59	14 715	40,22	97 263	109,46	39,89
2.70.4	ex 0805 20 70 ex 0805 20 90	— Tangerines and others	43,39	1 714	327,88	83,31	285,25	12 583	34,39	83 167	93,59	34,11
2.80	ex 0805 30 10	Lemons (<i>Citrus limon</i> , <i>Citrus limonum</i>), fresh	53,89	2 130	407,29	103,49	354,32	15 630	42,72	103 307	116,26	42,37
2.85	ex 0805 30 90	Limes (<i>Citrus aurantifolia</i>), fresh	71,02	2 807	536,67	136,36	466,88	20 595	56,29	136 125	153,20	55,84
2.90		Grapefruit, fresh :										
2.90.1	ex 0805 40 00	— white	43,95	1 737	332,16	84,40	288,97	12 747	34,84	84 252	94,82	34,56
2.90.2	ex 0805 40 00	— pink	47,17	1 864	356,47	90,57	310,11	13 680	37,39	90 417	101,75	37,09
2.100	0806 10 11 0806 10 15 0806 10 19	Table grapes	84,64	3 345	639,59	162,51	556,42	24 545	67,09	162 231	182,58	66,55
2.110	0807 10 10	Water-melons	38,86	1 536	293,70	74,63	255,51	11 271	30,80	74 497	83,84	30,56
2.120		Melons (other than water-melons) :										
2.120.1	ex 0807 10 90	— Amarillo, Cuper, Honey dew (including Cantalene), Onteniente, Piel de Sapo (including Verde Liso), Rochet, Tendral, Futuro	129,47	5 117	978,35	248,59	851,13	37 545	102,62	248 155	279,28	101,80
2.120.2	ex 0807 10 90	— other	55,93	2 210	422,67	107,40	367,71	16 220	44,33	107 209	120,65	43,98
2.130	0808 10 31 0808 10 33 0808 10 39 0808 10 51 0808 10 53 0808 10 59 0808 10 81 0808 10 83 0808 10 89	Apples	80,52	3 182	608,44	154,60	529,32	23 350	63,82	154 330	173,68	63,31
2.140		Pears										
2.140.1	0808 20 31 0808 20 33 0808 20 35 0808 20 39	Pears — Nashi (<i>Pyrus pyrifolia</i>)	156,13	6 174	1 175,83	299,97	1 025,47	45 343	124,61	297 483	336,47	123,14
2.140.2	0808 20 31 0808 20 33 0808 20 35 0808 20 39	Other	67,11	2 652	507,11	128,85	441,17	19 461	53,19	128 628	144,76	52,76

Code	CN code	Description	Amount of unit values per 100 kg net									
			ECU	Bfrs/Lfrs	Dkr	DM	FF	Dr	£ Irl	Lit	Fl	£
2.150	0809 10 00	Apricots	85,68	3 388	645,25	164,61	562,73	24 882	68,38	163 247	184,64	67,57
2.160	0809 20 20] 0809 20 40] 0809 20 60] 0809 20 80]	Cherries	155,38	6 144	1 170,13	298,51	1 020,50	45 123	124,00	296 043	334,84	122,54
2.170	ex 0809 30 90	Peaches	73,54	2 928	555,49	142,26	484,19	21 360	57,98	137 634	159,51	56,63
2.180	ex 0809 30 10	Nectarines	207,11	8 235	1 565,19	400,15	1 372,35	59 102	163,75	382 787	449,15	159,80
2.190	0809 40 11] 0809 40 19]	Plums	95,12	3 759	718,77	182,63	625,30	27 584	75,39	182 313	205,18	74,78
2.200	0810 10 10] 0810 10 90]	Strawberries	129,34	5 146	981,42	250,04	857,09	36 754	102,32	239 858	280,66	99,56
2.205	0810 20 10	Raspberries	1 232,1	49 408	9 305,36	2 396,74	8 133,50	344 866	961,01	2 323 153	2 685,64	922,33
2.210	0810 40 30	Fruit of the species <i>Vaccinium myrtillus</i>	194,02	7 673	1 461,18	372,77	1 274,33	56 347	154,85	369 677	418,12	153,02
2.220	0810 90 10	Kiwi fruit (<i>Actinidia chinensis</i> Planch.)	111,93	4 424	845,85	214,92	735,86	32 461	88,72	214 548	241,45	88,01
2.230	ex 0810 90 80	Pomegranates	48,29	1 953	364,38	93,69	318,81	13 439	37,52	91 577	105,04	35,97
2.240	ex 0810 90 80	Khakis (including Sharon fruit)	230,59	9 119	1 736,52	443,01	1 514,46	66 965	184,03	439 339	496,92	181,86
2.250	ex 0810 90 30	Lychees	503,66	19 918	3 792,95	967,63	3 307,92	146 267	401,96	959 610	1 085,38	397,22

COMMISSION REGULATION (EC) No 2034/94

of 10 August 1994

fixing the export refunds on white sugar and raw sugar exported in its unaltered state

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1785/81 of 30 June 1981 on the common organization of the markets in the sugar sector⁽¹⁾, as last amended by Regulation (EC) No 133/94⁽²⁾, and in particular point (a) of the first subparagraph of Article 19 (4) thereof,

Whereas Article 19 of Regulation (EEC) No 1785/81 provides that the difference between quotations or prices on the world market for the products listed in Article 1 (1) (a) of that Regulation and prices for those products within the Community may be covered by an export refund;

Whereas Council Regulation (EEC) No 766/68 of 18 June 1968 laying down general rules for granting export refunds on sugar⁽³⁾, as last amended by Regulation (EEC) No 1489/76⁽⁴⁾, provides that when refunds on white and raw sugar, undenatured and exported in its unaltered state are being fixed account must be taken of the situation on the Community and world markets in sugar and in particular of the price and cost factors set out in Article 3 of that Regulation; whereas the same Article provides that the economic aspect of the proposed exports should also be taken into account;

Whereas the refund on raw sugar must be fixed in respect of the standard quality; whereas the latter is defined in Article 1 of Council Regulation (EEC) No 431/68 of 9 April 1968 determining the standard quality for raw sugar and fixing the Community frontier crossing point for calculating cif prices for sugar⁽⁵⁾; whereas, furthermore, this refund should be fixed in accordance with Article 5 (2) of Regulation (EEC) No 766/68; whereas candy sugar is defined in Commission Regulation (EEC) No 394/70 of 2 March 1970 on detailed rules for granting export refunds on sugar⁽⁶⁾, as last amended by Regulation (EC) No 1555/94⁽⁷⁾; whereas the refund thus calculated for sugar containing added flavouring or colouring matter must apply to their sucrose content and, accordingly, be fixed per 1 % of the said content;

Whereas the world market situation or the specific requirements of certain markets may make it necessary to vary the refund for sugar according to destination;

Whereas, in special cases, the amount of the refund may be fixed by other legal instruments;

Whereas Council Regulation (EEC) No 990/93⁽⁸⁾ prohibits trade between the European Community and the Federal Republic of Yugoslavia (Serbia and Montenegro); whereas this prohibition does not apply in certain situations as comprehensively listed in Articles 2, 4, 5 and 7 thereof; whereas account should be taken of this fact when fixing the refunds;

Whereas the representative market rates defined in Article 1 of Council Regulation (EEC) No 3813/92⁽⁹⁾, as amended by Regulation (EC) No 3528/93⁽¹⁰⁾, are used to convert amounts expressed in third country currencies and are used as the basis for determining the agricultural conversion rates of the Member States' currencies; whereas detailed rules on the application and determination of these conversions were set by Commission Regulation (EEC) No 1068/93⁽¹¹⁾, as amended by Regulation (EC) No 547/94⁽¹²⁾;

Whereas the refund must be fixed every two weeks; whereas it may be altered in the intervening period;

Whereas it follows from applying the rules set out above to the present situation on the market in sugar and in particular to quotations or prices for sugar within the Community and on the world market that the refund should be as set out in the Annex hereto;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Sugar,

HAS ADOPTED THIS REGULATION:

Article 1

The export refunds on the products listed in Article 1 (1) (a) of Regulation (EEC) No 1785/81, undenatured and exported in the natural state, are hereby fixed to the amounts shown in the Annex hereto.

Article 2

This Regulation shall enter into force on 11 August 1994.

⁽¹⁾ OJ No L 177, 1. 7. 1981, p. 4.

⁽²⁾ OJ No L 22, 27. 1. 1994, p. 7.

⁽³⁾ OJ No L 143, 25. 6. 1968, p. 6.

⁽⁴⁾ OJ No L 167, 26. 6. 1976, p. 13.

⁽⁵⁾ OJ No L 89, 10. 4. 1968, p. 3.

⁽⁶⁾ OJ No L 50, 4. 3. 1970, p. 1.

⁽⁷⁾ OJ No L 166, 1. 7. 1994, p. 52.

⁽⁸⁾ OJ No L 102, 28. 4. 1993, p. 14.

⁽⁹⁾ OJ No L 387, 31. 12. 1992, p. 1.

⁽¹⁰⁾ OJ No L 320, 22. 12. 1993, p. 32.

⁽¹¹⁾ OJ No L 108, 1. 5. 1993, p. 106.

⁽¹²⁾ OJ No L 69, 12. 3. 1994, p. 1.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 August 1994.

For the Commission

René STEICHEN

Member of the Commission

ANNEX

to the Commission Regulation of 10 August 1994 fixing the export refunds on white sugar and raw sugar exported in its unaltered state

Product code	Amount of refund ⁽¹⁾
	— ECU/100 kg —
1701 11 90 100	32,45 ⁽¹⁾
1701 11 90 910	30,33 ⁽¹⁾
1701 11 90 950	⁽²⁾
1701 12 90 100	32,45 ⁽¹⁾
1701 12 90 910	30,33 ⁽¹⁾
1701 12 90 950	⁽²⁾
	— ECU/1 % of sucrose × 100 kg —
1701 91 00 000	0,3528
	— ECU/100 kg —
1701 99 10 100	35,28
1701 99 10 910	35,18
1701 99 10 950	33,68
	— ECU/1 % of sucrose × 100 kg —
1701 99 90 100	0,3528

⁽¹⁾ Applicable to raw sugar with a yield of 92 %; if the yield is other than 92 %, the refund applicable is calculated in accordance with the provisions of Article 5 (3) of Regulation (EEC) No 766/68.

⁽²⁾ Fixing suspended by Commission Regulation (EEC) No 2689/85 (OJ No L 255, 26. 9. 1985, p. 12), as amended by Regulation (EEC) No 3251/85 (OJ No L 309, 21. 11. 1985, p. 14).

⁽³⁾ Refunds on exports to the Federal Republic of Yugoslavia (Serbia and Montenegro) may be granted only where the conditions laid down in Regulation (EEC) No 990/93 are observed.

COMMISSION REGULATION (EC) No 2035/94

of 10 August 1994

fixing the maximum export refund for white sugar for the 11th partial invitation to tender issued within the framework of the standing invitation to tender provided for in Regulation (EC) No 1021/94

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1785/81 of 30 June 1981 on the common organization of the markets in the sugar sector⁽¹⁾, as last amended by Regulation (EC) No 133/94⁽²⁾, and in particular the first subparagraph of Article 19 (4) (b) thereof,

Whereas Commission Regulation (EC) No 1021/94 of 29 April 1994 on a standing invitation to tender to determine levies and/or refunds on exports of white sugar⁽³⁾ requires partial invitations to tender to be issued for the export of this sugar;

Whereas, pursuant to Article 9 (1) of Regulation (EC) No 1021/94, a maximum export refund shall be fixed, as the case may be, account being taken in particular of the state and foreseeable development of the Community and world markets in sugar, for the partial invitation to tender in question;

Whereas, following an examination of the tenders submitted in response to the 11th partial invitation to tender, the provisions set out in Article 1 should be adopted;

Whereas Council Regulation (EEC) No 990/93⁽⁴⁾ prohibits trade between the European Community and the

Federal Republic of Yugoslavia (Serbia and Montenegro); whereas this prohibition does not apply in certain situations as comprehensively listed in Articles 2, 4, 5 and 7 thereof; whereas account should be taken of this fact when fixing the refunds;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Sugar,

HAS ADOPTED THIS REGULATION:

Article 1

1. For the 11th partial invitation to tender for white sugar issued pursuant to Regulation (EC) No 1021/94 the maximum amount of the export refund is fixed at ECU 37,712 per 100 kilograms.
2. Refunds on exports to the Federal Republic of Yugoslavia (Serbia and Montenegro) may be granted only where the conditions laid down in Regulation (EEC) No 990/93 are observed.

Article 2

This Regulation shall enter into force on 11 August 1994.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 August 1994.

For the Commission

René STEICHEN

Member of the Commission

⁽¹⁾ OJ No L 177, 1. 7. 1981, p. 4.

⁽²⁾ OJ No L 22, 27. 1. 1994, p. 7.

⁽³⁾ OJ No L 112, 3. 5. 1994, p. 13.

⁽⁴⁾ OJ No L 102, 28. 4. 1993, p. 14.

COMMISSION REGULATION (EC) No 2036/94

of 10 August 1994

introducing a countervailing charge on certain varieties of plum originating in Romania

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1035/72 of 18 May 1972 on the common organization of the market in fruit and vegetables⁽¹⁾, as last amended by Regulation (EC) No 3669/93⁽²⁾, and in particular the second subparagraph of Article 27 (2) thereof,

Whereas Article 25 (1) of Regulation (EEC) No 1035/72 provides that, if the entry price of a product imported from a third country remains at least 0,6 ECU below the reference price for two consecutive market days, a countervailing charge must be introduced in respect of the exporting country concerned, save in exceptional circumstances; whereas this charge is equal to the difference between the reference price and the arithmetic mean of the last two entry prices available for that exporting country;

Whereas Commission Regulation (EC) No 1324/94 of 8 June 1994 fixing for the 1994 marketing year the reference prices for plums⁽³⁾ fixed the reference price for class I, group I at ECU 69,39 per 100 kilograms net for the month of August 1994;

Whereas the entry price for a given exporting country is equal to the lowest representative prices recorded for at least 30 % of the quantities from the exporting country concerned which are marketed on all representative markets for which prices are available, less the duties, and the charges indicated in Article 24 (3) of Regulation (EEC) No 1035/72; whereas the meaning of representative price is defined in Article 24 (2) of Regulation (EEC) No 1035/72;

Whereas, in accordance with Article 3 (1) of Commission Regulation (EEC) No 2118/74⁽⁴⁾, as last amended by Regulation (EEC) No 249/93⁽⁵⁾, the prices to be taken

into consideration must be recorded on the representative markets or, in certain circumstances, on other markets;

Whereas, for plums of group I originating in Romania the entry price calculated in this way has remained at least ECU 0,6 below the reference price for two consecutive market days; whereas a countervailing charge should therefore be introduced for these plums;

Whereas the representative market rates defined in Article 1 of Council Regulation (EEC) No 3813/92⁽⁶⁾, as amended by Regulation (EC) No 3528/93⁽⁷⁾, are used to convert amounts expressed in third country currencies and are used as the basis for determining the agricultural conversion rates of the Member States' currencies; whereas detailed rules on the application and determination of these conversions were set by Commission Regulation (EEC) No 1068/93⁽⁸⁾, as amended by Regulation (EC) No 547/94⁽⁹⁾,

HAS ADOPTED THIS REGULATION:

Article 1

A countervailing charge of ECU 24,14 per 100 kilograms net is applied to plums (CN codes 0809 40 11 and 0809 40 19), other than the following varieties: Altesse simple (common quetsche, Hauszwetschge), Reine-Claude d'Oullins (Oullins Gage), Sveskeblommer, Ruth Gerstetter, Ontario, Wangenheimer (early Wangenheim quetsche), Pershore (Yellow Egg), Mirabelle and Bosnische originating in Romania.

Article 2

This Regulation shall enter into force on 12 August 1994.

⁽¹⁾ OJ No L 118, 20. 5. 1972, p. 1.

⁽²⁾ OJ No L 338, 31. 12. 1993, p. 26.

⁽³⁾ OJ No L 144, 9. 6. 1994, p. 7.

⁽⁴⁾ OJ No L 220, 10. 8. 1974, p. 20.

⁽⁵⁾ OJ No L 28, 5. 2. 1993, p. 45.

⁽⁶⁾ OJ No L 387, 31. 12. 1992, p. 1.

⁽⁷⁾ OJ No L 320, 22. 12. 1993, p. 32.

⁽⁸⁾ OJ No L 108, 1. 5. 1993, p. 106.

⁽⁹⁾ OJ No L 69, 12. 3. 1994, p. 1.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 August 1994.

For the Commission

René STEICHEN

Member of the Commission

COMMISSION REGULATION (EC) No 2037/94

of 10 August 1994

introducing a countervailing charge on certain varieties of plum originating in Hungary

THE COMMISSION OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1035/72 of 18 May 1972 on the common organization of the market in fruit and vegetables⁽¹⁾, as last amended by Regulation (EC) No 3669/93⁽²⁾, and in particular the second subparagraph of Article 27 (2) thereof,

Whereas Commission Regulation (EC) No 1985/94⁽³⁾, introduced a countervailing charge on certain varieties of plum originating in Hungary;

Whereas for these varieties of plum originating in Hungary there were no prices for six consecutive working

days; whereas the conditions specified in Article 26 (1) of Regulation (EEC) No 1035/72 are therefore fulfilled and the countervailing charge on imports of certain varieties of plum originating in Hungary can be abolished,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1985/94 is hereby repealed.

Article 2

This Regulation shall enter into force on 11 August 1994.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 August 1994.

For the Commission

René STEICHEN

Member of the Commission

⁽¹⁾ OJ No L 118, 20. 5. 1972, p. 1.

⁽²⁾ OJ No L 338, 31. 12. 1993, p. 26.

⁽³⁾ OJ No L 199, 2. 8. 1994, p. 37.

COMMISSION REGULATION (EC) No 2038/94
of 10 August 1994

concerning Regulation (EC) No 1606/94 relating to the exemption from the import levy for certain products in the cereals sector laid down in the Agreements between the European Community, on the one part and the Republic of Bulgaria and Romania on the other part

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992 on the common organization of the market in cereals⁽¹⁾, as last amended by Regulation (EC) No 1866/94⁽²⁾, and in particular Article 9 thereof,

Whereas Commission Regulation (EC) No 1606/94 of 1 July 1994 relating to the exemption from the import levy for certain products in the cereals sector laid down in the Agreements between the European Community and the Republic of Bulgaria and Romania⁽³⁾, as last amended by Regulation (EC) No 1906/94⁽⁴⁾, specifies the quantity of common wheat originating in Bulgaria which enjoy preferential access under the Interim Agreement concluded with that country;

Whereas the Commission must fix a single coefficient for reducing the quantities in the import licences applied for where these quantities exceed the quantities in the annual quota; whereas applications for import licences submitted

on 8 August 1994 for common wheat from Bulgaria related to 3 800 tonnes and the maximum quantity that may be imported is 1 900 tonnes at a levy reduced by 60 %; whereas the corresponding percentage reductions for import licence applications submitted on 8 August 1994 should be fixed,

HAS ADOPTED THIS REGULATION:

Article 1

Applications for licences for 'Bulgaria' quota provided for in Regulation (EC) No 1606/94 at a levy reduced by 60 % for common wheat falling within CN code 1001 90 99 submitted on 8 August 1994 and forwarded to the Commission, shall be accepted for the tonnages indicated therein multiplied by a coefficient of 0,5.

Article 2

This Regulation shall enter into force on 11 August 1994.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 August 1994.

For the Commission

René STEICHEN

Member of the Commission

⁽¹⁾ OJ No L 181, 1. 7. 1992, p. 21.

⁽²⁾ OJ No L 197, 30. 7. 1994, p. 1.

⁽³⁾ OJ No L 168, 2. 7. 1994, p. 13.

⁽⁴⁾ OJ No L 194, 29. 7. 1994, p. 26.

COMMISSION REGULATION (EC) No 2039/94

of 10 August 1994

fixing the import levies on white sugar and raw sugar

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1785/81 of 30 June 1981 on the common organization of the markets in the sugar sector⁽¹⁾, as last amended by Regulation (EC) No 133/94⁽²⁾, and in particular Article 16 (8) thereof,

Having regard to Council Regulation (EEC) No 3813/92 of 28 December 1992 on the unit of account and the conversion rates to be applied for the purposes of the common agricultural policy⁽³⁾, as amended by Regulation (EC) No 3528/93⁽⁴⁾, and in particular Article 5 thereof,

Whereas the import levies on white sugar and raw sugar were fixed by Commission Regulation (EC) No 1957/94⁽⁵⁾, as last amended by Regulation (EC) No 2022/94⁽⁶⁾;

Whereas it follows from applying the detailed rules contained in Commission Regulation (EC) No 1957/94 to the information known to the Commission that the levies

at present in force should be altered to the amounts set out in the Annex hereto;

Whereas, in order to make it possible for the levy arrangements to function normally, the representative market rate established during the reference period from 9 August 1994, as regards floating currencies, should be used to calculate the levies,

HAS ADOPTED THIS REGULATION:

Article 1

The import levies referred to in Article 16 (1) of Regulation (EEC) No 1785/81 shall be, in respect of white sugar and standard quality raw sugar, as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 11 August 1994.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 August 1994.

For the Commission

René STEICHEN

Member of the Commission

⁽¹⁾ OJ No L 177, 1. 7. 1981, p. 4.

⁽²⁾ OJ No L 22, 27. 1. 1994, p. 7.

⁽³⁾ OJ No L 387, 31. 12. 1992, p. 1.

⁽⁴⁾ OJ No L 320, 22. 12. 1993, p. 32.

⁽⁵⁾ OJ No L 198, 30. 7. 1994, p. 88.

⁽⁶⁾ OJ No L 203, 6. 8. 1994, p. 12.

ANNEX

to the Commission Regulation of 10 August 1994 fixing the import levies on white sugar and raw sugar

(ECU/100 kg)

CN code	Levy ⁽²⁾
1701 11 10	33,14 ⁽¹⁾
1701 11 90	33,14 ⁽¹⁾
1701 12 10	33,14 ⁽¹⁾
1701 12 90	33,14 ⁽¹⁾
1701 91 00	40,24
1701 99 10	40,24
1701 99 90	40,24 ⁽²⁾

⁽¹⁾ The levy applicable is calculated in accordance with the provisions of Article 2 or 3 of Commission Regulation (EEC) No 837/68 (OJ No L 151, 30. 6. 1968, p. 42), as last amended by Regulation (EEC) No 1428/78 (OJ No L 171, 28. 6. 1978, p. 34).

⁽²⁾ In accordance with Article 16 (2) of Regulation (EEC) No 1785/81 this amount is also applicable to sugar obtained from white and raw sugar containing added substances other than flavouring or colouring matter.

⁽³⁾ No import levy applies to OCT originating products according to Article 101 (1) of Decision 91/482/EEC.

COMMISSION REGULATION (EC) No 2040/94

of 10 August 1994

on the issue of import licences for high-quality fresh, chilled or frozen beef and veal

THE COMMISSION OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 129/94 of 24 January 1994 opening a Community tariff quota for high-quality fresh, chilled or frozen meat of bovine animals falling within CN codes 0201 and 0202 and for products falling within CN codes 0206 10 95 and 0206 29 91 (1994) (1), and in particular Article 2 thereof,

Whereas Commission Regulation (EC) No 212/94 of 31 January 1994 laying down detailed rules for the application of import arrangements provided for by Council Regulations (EC) No 129/94 and (EC) No 131/94 for high-quality beef and frozen buffalo meat (2) provides in Article 6, that applications for and the issue of import licences for the meat referred to in Article 1 (1) (d) thereof are to be effected in accordance with the provisions of Articles 12 and 15 of Commission Regulation (EEC) No 2377/80 of 4 September 1980 on special detailed rules for the application of the system of import and export licences in the beef and veal sector (3), as last amended by Regulation (EC) No 1084/94 (4);

Whereas Article 1 (1) (d) of Regulation (EC) No 212/94 fixes the amount of high-quality fresh, chilled or frozen

beef and veal originating in and imported from the United States of America and Canada which may be imported on special terms in 1994 at 10 000 tonnes;

Whereas it should be recalled that licences issued pursuant to this Regulation will, throughout the period of validity, be open for use only in so far as provisions on health protection in force permit,

HAS ADOPTED THIS REGULATION:

Article 1

1. All applications for import licences from 1 until 5 August 1994 for high-quality fresh, chilled or frozen beef and veal as referred to in Article 1 (1) (d) of Regulation (EC) No 212/94 shall be met in full.

2. Applications for licences may be submitted, in accordance with Article 15 of Regulation (EEC) No 2377/80, during the first five days of September 1994 for 6 248 tonnes.

Article 2

This Regulation shall enter into force on 11 August 1994.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 August 1994.

For the Commission

René STEICHEN

Member of the Commission

(1) OJ No L 22, 27. 1. 1994, p. 1.

(2) OJ No L 27, 1. 2. 1994, p. 38.

(3) OJ No L 241, 13. 9. 1980, p. 5.

(4) OJ No L 120, 11. 5. 1994, p. 30.

COMMISSION DIRECTIVE 94/40/EC

of 22 July 1994

amending Council Directive 87/153/EEC fixing guidelines for the assessment of additives in animal nutrition

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs⁽¹⁾, as last amended by Commission Directive 94/17/EC⁽²⁾, and in particular Article 9 (2) thereof,

Whereas Council Directive 70/524/EEC provides for guidelines for the assessment of additives in animal nutrition subsequently adopted by Council Directive 87/153/EEC⁽³⁾ and any amendment thereto in the light of advances in scientific and technical knowledge;

Whereas those guidelines should be supplemented by the establishment of criteria for examining requests for the authorization of enzymes and microorganisms for use as feed additives;

Whereas pursuant to the provisions of Council Directive 93/114/EC⁽⁴⁾ it is necessary to include in the Community procedure for the authorization of additives the requirements of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms⁽⁵⁾, as amended by Commission Directive 94/15/EC⁽⁶⁾ for a specific environmental-risk evaluation, in order that they may be applicable to all additives containing or consisting of genetically modified organisms; whereas as a consequence, it is appropriate to amend Directive 87/153/EEC in order to comply with the requirements of Directive 90/220/EEC;

Whereas, since numerous amendments have been made, it appears useful to provide a consolidation of the guidelines in the Annex to this Directive;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Feedingstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Annex to Directive 87/153/EEC is hereby replaced by the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations or administrative provisions necessary to comply with this Directive by 1 October 1994 at the latest. They shall immediately inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

Done at Brussels, 22 July 1994.

For the Commission

René STEICHEN

Member of the Commission

⁽¹⁾ OJ No L 270, 14. 12. 1970, p. 1.

⁽²⁾ OJ No L 105, 26. 4. 1994, p. 19.

⁽³⁾ OJ No L 64, 7. 3. 1987, p. 19.

⁽⁴⁾ OJ No L 334, 31. 12. 1993, p. 24.

⁽⁵⁾ OJ No L 117, 8. 5. 1990, p. 15.

⁽⁶⁾ OJ No L 103, 22. 4. 1994, p. 20.

ANNEX

GUIDELINES FOR THE ASSESSMENT OF ADDITIVES IN FEEDINGSTUFFS

GENERAL ASPECTS

These guidelines are intended as a guide for establishing dossiers on substances and preparations being submitted for authorization as additives in feedingstuffs. These dossiers must enable an assessment to be made of the additives based on the present state of knowledge and make it possible to ensure their compliance with the fundamental principles laid down for their admission, which are the subject of the provisions of Article 7 (2) of Directive 70/524/EEC.

All the studies outlined in these guidelines may be required and, if necessary, additional information will be requested. As a general rule, studies to establish the identity, conditions of use, physico-chemical properties, methods of determination and efficacy of the additive, and also its metabolism, biological and toxicological effects on target species must be provided. When the additive is intended for a category of animals belonging to a defined species, these studies must be performed on this target category. The studies necessary for the evaluation of risks to human health or the environment will depend essentially on the nature of the additive and the circumstances of its use. In this respect, no strict rule is applicable.

It may not always be necessary to subject additives intended exclusively for pet food to as exhaustive a program of chronic toxicity, mutagenicity and carcinogenicity testing as that required for additives intended for feeding to livestock from which products for human consumption are derived. To determine chronic toxicity, studies on two target species or on one target species and rats for a period of one year will generally suffice. Mutagenesis and carcinogenesis studies can generally be dispensed with if the chemical composition, practical experience, or other considerations do not indicate the likelihood of changes. It is possible to dispense with the analysis of residues in pet animals.

Knowledge of the metabolism of the additive in productive livestock and of the residues and their bio-availability is essential. In particular it must enable the extent of the toxicological studies to be performed on laboratory animals in order to assess the risks, if any, to the consumer to be determined. This evaluation cannot be based solely on data confined to determining the direct effects of the additives on laboratory animals. The latter does not provide specific information on the actual effects of residues resulting from the metabolism in the species for which the additive is intended.

Any application for authorization of an additive or a new usage for an additive shall be supported by a dossier which should include detailed reports presented in the order and with the numbering proposed in these guidelines. Reasons must be given for the omission from the dossier of any data prescribed in these guidelines. Publications to which reference is made must be attached to it the reports of experiments must include the plan, the reference number, the date of the beginning and the end of the experiment, detailed description of the tests, results and their analysis and also the name, address and signature of the person responsible for the study. Each batch of the feedingstuffs used in the experimental studies on animals must be analysed for the concentration of the relevant active substances using an appropriate method and a report of the analytical results must be provided. The report must also mention the individual doses determined in each experimental study, the corresponding dates, the name, address and signature of the person responsible for the controls. Furthermore, a certificate drawn up by the laboratory or laboratories where the experiments were conducted to the effect that the tests were carried out in accordance with the principles of good laboratory practices pursuant to Council Directive 87/18/EEC, on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances⁽¹⁾, must be attached to the report.

The determination of physico-chemical, toxicological and ecotoxicological properties shall be performed in accordance with the methods established by Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances⁽²⁾, as last amended by Commission Directive 93/105/EC⁽³⁾, or with methods internationally recognized by scientific bodies. The use of other methods should be justified.

⁽¹⁾ OJ No L 15, 17. 1. 1987, p. 29.

⁽²⁾ OJ No L 196, 16. 8. 1967, p. 1.

⁽³⁾ OJ No L 294, 30. 11. 1993, p. 21.

Each dossier shall contain an adequate summary. The dossiers relating to antibiotics, coccidiostats and other medicinal substances, growth promoters, microorganisms and/or enzyme preparations, must be accompanied by a monograph, conforming with the model provided in Section V, enabling the additive concerned to be identified and characterized in accordance with Article 8 (1) of Directive 70/524/EEC.

The term 'additive', as used in these guidelines, refers to the active substances or the preparations containing active substances in the state in which they will be incorporated in premixtures and feedingstuffs. An active substance may be a chemically specified substance, a microorganism or an enzyme preparation.

In these guidelines the expression 'Chemically specified substances', means chemical substances for which a chemical name is agreed according to IUPAC nomenclature.

The Commission must be notified within a reasonable time by the Member State which forwarded the dossier to it of any modification to the manufacturing process or the composition of an additive, its field of application or its conditions of use. This could necessitate the submission of documentation suitable for a new assessment. These requirements will be especially necessary for products derived from microorganisms, the genetic characteristics of which have been modified or which arise as natural mutants.

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SECTION I

SUMMARY OF THE DATA IN THE DOSSIER

SECTION II

IDENTITY, CHARACTERIZATION AND CONDITIONS OF USE OF THE ADDITIVE
METHODS OF CONTROL

1. Identity of the additive

- 1.1. Proposed proprietary name(s)
- 1.2. Type of additive according to its main function
- 1.3. Qualitative and quantitative composition (active substance, other components, impurities)
- 1.4. Physical state, particle size
- 1.5. Manufacturing process including any specific processing procedures

N.B. : If the active substance is a mixture of active components, each of which is clearly definable, the main components must be described separately and the proportions in the mixture given.

2. Specifications concerning the active substance

- 2.1. For chemically specified substances : generic name, chemical name according to Iupac nomenclature, other generic international names and abbreviations. Chemical Abstracts Service Number (CAS).

For microorganisms : name and taxonomic description according to the international Codes of Nomenclature. Other internationally recognized manuals of classification can also be used ⁽¹⁾.

For enzyme preparations : name according to main enzymatic activities as described by IUB/Iupac. Einecs and CAS Number.

- 2.2. Formula, empirical and structural, and molecular weight. Qualitative and quantitative composition of the main components, if the active substance is a fermentation product.

For microorganisms : name and place of culture collection, if possible one in an EC collection, where the strain is deposited and depositing number, genetic modification and all relevant properties for its identification. In addition, origin, appropriate morphological and physiological characteristics, developmental stages, relevant factors that may be involved in its biological activity (as an additive) and other genetic data for identification. Number of colony forming units (CFU) per gram.

For enzyme preparations : biological origin (in case of microbial origin : name and place of culture collection, if possible one in an EC collection, where the strain is deposited and depositing number, genetic modification and all relevant properties for its identification including genetic data), the activities towards relevant chemically pure model substrates and other physico-chemical characteristics.

2.3. Degree of purity

Qualitative and quantitative composition of the impurities.

For microorganisms : genetic stability and purity of strains cultivated.

For enzyme preparations :

- purity, by checking the level of contaminating microorganisms, heavy metals, absence of toxins derived from the source organism (e.g. mycotoxins), as shown by a suitable method ;
- absence of antimicrobial activity at feed concentration level as determined by a suitable method ;
- composition of the non-enzymatic components (particularly Total Organic Solids TOS ⁽²⁾).

2.4. Relevant properties

For chemically specified substances : Electrostatic properties, melting point, boiling point, decomposition temperature, density, vapour pressure, solubility in water and organic solvents, mass and absorption spectra and any other appropriate physical properties.

⁽¹⁾ Such as *Bergey's Manual of Systematic Bacteriology*, *The Yeasts, a taxonomic study* by Lodder and Krieger van Rij, *Ainsworth and Bisby's Dictionary of the Fungi* by Hawksworth, Sutton and Ainsworth or *The Genus Aspergillus* by Raper and Fennell.

⁽²⁾ TOS (%) = 100 - (% ash + water + % diluents and/or additives and ingredients).

For microorganisms : properties relevant to identification and proposed use (e.g. vegetative or sporulated form, CFU per g)

For enzyme preparations : optimal PH (value(s), optimal temperature(s) and other appropriate properties).

2.5. Manufacturing, purification processes and media used

Variation in the composition of the batches in the course of production.

3. Physico-chemical, technological and biological properties of the additive

3.1. Stability (for microorganisms : loss of biological activity, e.g. viability) on exposure to environmental conditions such as light, temperature, pH, moisture and oxygen. Shelf life.

3.2. Stability (for microorganisms : loss of biological activity, e.g. viability) during the preparation of premixtures and feedingstuffs, in particular stability to heat, pressure and moisture. Possible decomposition products.

3.3. Stability (for microorganisms : loss of biological activity, e.g. viability) during the storage of premixtures and feedingstuffs under defined conditions. Shelf life.

For enzyme preparations : Details of the presence of unexpected reaction products formed by either enzymatic or chemical reactions of the enzyme preparation with feed constituents or by degradation of the enzyme preparation during storage of the feedingstuff.

3.4. Other appropriate physico-chemical, technological or biological properties such as ability to obtain homogeneous mixtures in premixtures and feedingstuffs, dust-forming properties, and for microorganisms and/or enzyme preparations, assessment of resistance to degradation or loss of biological activity in the digestive tract or by systems of simulation in vitro.

3.5. Physico-chemical or biological incompatibilities or interactions (e.g. with feedingstuffs, other approved additives or with medicinal products).

4. Conditions of use of the additive

4.1. Proposed use in animal nutrition (e.g. species and category of animal, type of feedingstuff, period of administration and withdrawal period).

4.2. Contra-indications

4.3. Proposed dosing in premixtures and feedingstuffs expressed as :

- a percentage of the active substance by weight for premixtures and as mg/kg for feedingstuffs, in case of chemically specified substances,
- appropriate units of biological activity such as CFU per gram of product for microorganisms or relevant activity units for enzyme preparations.

4.4. Other known uses of the active substance or the preparation (e.g. in foodstuffs, human or veterinary medicine, agriculture and industry). For each use give the proprietary names, indications and contra-indications.

4.5. If necessary, measures for the prevention of risks and means of protection during manufacture and handling.

5. Control methods

5.1. Description of the methods used for the determination of the criteria listed under items 1.3., 2.3., 2.4., 2.5., 3.1., 3.2., 3.3., 3.4. and 4.3.

5.2. Description of the qualitative and quantitative analytical methods for routine control of the additive in premixtures and feedingstuffs.

5.3. Description of the qualitative and quantitative analytical methods for determining residues of additives in animal produce.

N.B. The methods specified and the results should be accompanied by information as to percentage recovery, specificity, sensitivity, limits of detection, possible interferences, reproducibility and to the sampling method used. Reference standards of the preparation and of the active substance must be available.

In the case of microorganisms state methods of detection, enumeration, identification and relevant markets.

SECTION III

STUDIES CONCERNING THE EFFICACY OF THE ADDITIVE

1. Studies concerning improvements in the characteristics of feedingstuffs

These studies concern technological additives such as antioxidants, preservatives, binders, emulsifiers, stabilizers, gelling agents etc., which are intended to improve or stabilize the characteristics of premixtures and feedingstuffs. Some microorganisms and/or enzyme preparations could also be considered as technological additives, if they improve relevant feed characteristics.

Evidence of the efficacy of the additive should be provided by means of appropriate criteria under the intended conditions of use in comparison with negative control feedingstuffs and, possibly, feedingstuffs containing technological additives of known effectiveness.

The precise nature of the active substances, preparations, premixes and feedingstuffs examined, the reference number of the batches, the concentration of the active substances in premixtures and feedingstuffs, the testing conditions (e.g. temperature and humidity) and also the dates and duration of testing, the adverse and negative effects which occurred during testing shall be specified for each experiment

2. Studies concerning the effects of additives on animal production

These studies concern zootechnical additives which have effects on animal production. The following studies, including dose/response relationship, should be performed on each target species in comparison with negative control groups and, possibly, groups receiving feedingstuffs containing additives of known effectiveness.

If the active substance is a mixture of active components, the presence of each component must be justified.

2.1. For coccidiostats and other medicinal substances, importance should primarily be attached to evidence of the specific effects and particularly prophylactic properties (e.g. morbidity, oocyst count and lesion score). Information on the effect on feed efficiency, animal growth and marketable quantity and quality of the animal produce may be added.

2.2. For other zootechnical additives (including if appropriate microorganisms and/or enzyme preparations) information should be provided on the effects on: nutritional efficiency, animal growth, animal-product characteristics and yield, animal welfare and other parameters having a positive influence on animal production.

2.3. *Experimental conditions*

The test performed must be described and the results presented individually in detail. The statistical evaluation and the methods employed should be reported. The following data must be provided:

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

2.3.2. Number of test and control groups, number of animals in each group. The number of animals of both sexes must be sufficient for statistical purposes.

2.3.3. Concentration of the active substance (and, where it is the case, substances used for comparative purposes) in the feedingstuffs established by a control analysis, using the appropriate recognized method. Reference number of the batches. Nutritional composition of the diet in terms of quality and quantity.

2.3.4. Location of each experiment. Animal health, physiological, feeding and rearing conditions as usually practised in the Community. Feed control and measures taken to avoid contamination of control groups during the experiment (particularly for microorganisms through cross-contamination of feed by the microorganism).

2.3.5. Date and exact duration of testing. Date and nature of examinations performed.

2.3.6. Unfavourable effects and other incidents which occurred during the experiment and time of their appearance.

3. Studies concerning the quality of animal produce

Studies on the organoleptic, nutritional, hygienic and technological qualities of produce from animals fed with feedingstuffs containing the additive.

SECTION IV

STUDIES CONCERNING THE SAFETY OF USE OF THE ADDITIVE

The studies outlined in this section are intended to permit assessment of :

- the safety of use of the additive in the target species,
- the from risks inhalation, other mucosal, eye or cutaneous contact for persons likely to handle the additive as such or as incorporated into premixtures or feedingstuffs,
- the risks to the consumer which could result from the consumption of food containing residues of the additive, or its metabolites,
- the risks of pollution or persistence in the environment from the additive itself or by products derived from the additive and excreted by animals,
- possible risks to non-target species.

These studies will be required in their entirety or in part depending on the nature of the additive and the conditions proposed for its use.

As a general principle microorganisms and/or enzyme preparations must be, or be derived from microorganisms that are non-pathogenic and non-toxicogenic for target species and humans under the expected conditions of use.

In the case of microorganisms and/or enzyme preparations appropriate safety tests must be performed, unless other satisfactory documentation for safety of use is provided. For microorganisms at least a tolerance test on target species must be performed.

In principle toxicological tests for enzymes derived from edible parts of animals or plants are not required ; where such products are not generally considered a normal part of the diet used, some toxicological testing may be required.

If the active substance is chemically specified the knowledge of their metabolism in the various target species and also of the composition and the bio-availability of the tissue residues will be essential for determining the extent of studies on laboratory animals to assess the risks for the consumer. Furthermore, knowledge of the composition and of the physico-chemical and biological properties of the excreted residues deriving from the additive will be indispensable to define the extent of the studies necessary for assessment of the risk of pollution or persistence in the environment.

1. Studies on target species

1.1. *Toxicological studies of the additive*

Tolerance tests

Study of the biological, toxicological, macroscopic and histological effects. Determination of the safety margin between the maximum proposed dose-level and the level resulting in unfavourable effects. It may be sufficient to indicate a minimum or approximate value for this margin if it can be shown that the level resulting in unfavourable effects greatly exceeds the maximum proposed dose-level.

1.2. *Microbiological studies of the additive*

1.2.1. If the active substance is chemically specified and possesses antimicrobial activity at feed concentration level, studies of the antibacterial spectrum of action of the additive by determination of the minimum inhibition concentration (MIC) in various pathogenic and non-pathogenic Gram-negative and Gram-positive species of bacteria must be provided.

1.2.2. Studies on the cross-resistance to therapeutic antibiotics by determination of the MIC, in mutants produced in vitro which exhibit chromosomal resistance to the additive. In the case of microorganisms which are resistant to therapeutic antibiotics, the genetic basis of this resistance should be shown.

1.2.3. Tests to find out whether the additive is capable of selecting resistance factors. These tests are to be performed under field conditions in the animal species for which the additive is primarily intended. Subsequently, it should be determined whether R factors which may have been found carry multiple resistance and are transmissible.

- 1.2.4. Tests to determine the effect of the additive,
- on the microflora of the digestive tract,
 - on the colonization of the digestive tract, if it is a microorganism or a mixture of several strains of microorganisms,
 - on the shedding or excretion of pathogenic microorganisms, if the active substance is chemically specified and has antimicrobial activity.
- 1.2.5. In cases where the active substance shows an antimicrobial action, field studies to monitor the percentage of bacteria resistant to the additive should be provided. These are to be carried out at major intervals before, during and after (one month) the use of the additive.
- 1.2.6. If the active substance is a microorganism, it should be determined if it is resistant to antibiotics.
- 1.2.7. If the active substance (e.g. enzyme preparations) is produced by a microorganism the level of the respective viable organism should be determined.
- 1.2.8. If the additive contains or consists of a genetically modified organism within the meaning of Article 2 (1) and (2) of Council Directive 90/220/EEC the following information must be provided:
- A copy of any written consent or consents of the competent authorities to the deliberate release of the genetically modified organisms for research and development purposes pursuant to Article 6 (4) of Directive 90/220/EEC and the summary of the notification as referred in Article 9 of Directive 90/220/EEC according to the model set up in Council Decision 91/596/EEC⁽¹⁾;
 - the complete technical file with the information required in Annex II of Directive 90/220/EEC, extended as necessary to take into account the diversity of sites of use of the additive, including information on data and results obtained from research and developmental releases concerning the ecosystems which could be affected by the use of the additive and an assessment of any risks for human health, animal health and the environment related to the GMO(s) contained in the product including information obtained from the research and development stage on the impact of the release on human health and the environment;
 - the conditions for the placing on the market of the additive, including specific conditions of use and handling and a proposal for labelling and packaging which should comprise at least the requirements laid down in Annex III of Directive 90/220/EEC.

If on the basis of any release notified under Part B of Directive 90/220/EEC, or on substantive, reasoned scientific grounds, the person responsible for the dossier considers that the placing on the market or the use of the additive does not pose a risk to human health, animal health and the environment, he may propose not to comply with one or more of the requirements of Annex III B.

Information on data or results from releases of the same GMO or the same combination of GMOs previously or currently notified and/or carried out by the person responsible for the dossier either inside or outside of Community, shall be included.

Other data or results from notifications previously submitted by other persons may also be referred, provided that the latter have given their agreement in writing.

1.3. *Studies of the metabolism and residues⁽²⁾ ⁽³⁾ (If the active substance is chemically specified).*

1.3.1. Study of metabolism,

- metabolic balance: rate and extent of absorption and elimination of the active substance,
- identification of the metabolic pathways and main metabolites,
- distribution and excretion (biliary, urinary, faecal) of the metabolites,
- if appropriate, influence of the intestinal or ruminal microflora, of enterohepatic cycle, of caecotrophy, on the metabolism.

1.3.2. Analytical studies of the residues: qualitative and quantitative composition of the residues (active substance, metabolites) in the various animal food products at metabolic equilibrium and under practical conditions of use of the additive.

⁽¹⁾ OJ No L 322, 23. 11. 1991, p. 1.

⁽²⁾ The studies mentioned under 1.3.1., 1.3.3. and 1.3.4. should be carried out with labelled molecules or other appropriate methods, in each case the choice of the method utilized should be justified. The labelling should be suitable for the purpose intended.

⁽³⁾ If the active substance is produced by fermentation, these studies should be extended to related substances derived from the production process.

- 1.3.3. Kinetic study of the residues (following repeated administration of the additive according to the purposal use): persistence of the active substance and the main metabolites in the various organs and tissues after withdrawal of the supplemented feedingstuff.
- 1.3.4. Study of the bio-availability of the residues in animal food products. (see 3.7.).
- 1.3.5. Methods of monitoring: qualitative and quantitative method of determination used in the studies mentioned under items 1.3.1. to 1.3.4. with information as to percentage recovery, specificity and limits of detection. The methods of determination of the residues must be sufficiently sensitive to permit detection of residues at levels which are toxicologically negligible.

2. Study on excreted residues (where the active substance is chemically specified)

- 2.1. Nature and concentration of the residues derived from the additive (active substance, metabolites) in the excreta.
- 2.2. Persistence (half-life value) and kinetics of elimination of these residues in slurries, farm yard manure and litter.
- 2.3. Effects on methanogenesis.
- 2.4. Degradation, persistence (half-life value) and kinetics of elimination in soils (contrasting soil types).
- 2.5. Effects on soil fauna and microbial processes of transformation (e.g. decomposition of plant and animal residues).
- 2.6. Effects on terrestrial plants (e.g. seed germination, plant growth and plant uptake). These studies should be carried out under controlled conditions and field conditions, using different plant species.
- 2.7. Solubility and stability in water of the products derived from the additive (active substance, metabolites).
- 2.8. *Effects on aquatic life*
 - 2.8.1. Effects on flora (e.g. Chlorella).
 - 2.8.2. Toxicity in non-vertebrates (e.g. Daphnia magna).
 - 2.8.3. Toxicity in fish (at least two wild species found in the Community territory).

3. Studies on laboratory animals

These studies must be carried out with the active substance and its major metabolites or products, if the latter are also present in edible animal produce and are bioavailable. As far as possible attempts should be made to select laboratory animals which may be expected to digest and metabolize the additive in a similar way to man or the target species.

Full detailed descriptions must be provided of the tests performed. These should cover the animal species and strains employed, the size and number of test and control groups, the dose levels administered, the composition of the diet and the results of feed analyses, the rearing conditions, the exact duration of the tests, the dates of the various examinations performed and mortality. Full details must be given of the macroscopic pathological and histopathological findings in all animals tested with an indication of the time of appearance of all pathological lesions. All results, including statistical assessment, must be presented in detail.

- 3.1. *Acute toxicity (not relevant for microorganisms)*
 - 3.1.1. Acute oral toxicity studies must be carried out on two animal species (preferably the rat should be one). The maximum dosage should not be higher than 2,000 mg/kg body weight. Detailed observations should be reported of the biological effects observed during a period of at least two weeks after ingestion. These studies are not relevant for enzyme preparations.
 - 3.1.2. Studies on acute inhalational toxicity, skin and, where necessary, mucous membranes irritancy and also allergenic potential must be performed by appropriate tests for the assessment of possible risks associated with the handling of the additive.
- 3.2. *Mutagenicity*
 - 3.2.1. If the active substance is chemically specified

In order to identify active substances or their metabolites or products that possess mutagenic properties a selected combination of mutagenicity tests, based on different genetic endpoints, must be carried out. Tests must be performed, in the presence and absence of a microsomal mammalian preparation, for metabolic activation.

The following package of tests is recommended :

- (a) a test for gene mutations in a prokaryotic system,
- (b) a test for gene mutations in an *in-vitro* eukaryotic system or a sex-linked recessive lethal test in *Drosophila melanogaster*,
- (c) a test for chromosomal aberrations *in-vitro* and *in-vivo*.

The battery of tests suggested above does not imply, however, that other tests are inappropriate or that other tests, in particular *in-vivo* tests, would not be acceptable as alternatives.

In all cases reasons for the choice of tests should be given. Tests must be carried out according to established validated procedures. Depending on the outcome of the tests and taking into consideration the whole toxicity profile of the substance as well as the intended use, additional investigations may be indicated.

- 3.2.2. In the case of enzyme preparations derived from microorganisms the following tests are normally required :

- (a) a test for gene mutations in bacteria,
- (b) a test for chromosomal aberrations (preferably *in vitro*).

The toxicological tests shall, where possible, be performed on a batch from the final purified fermentation product, before addition of carriers, diluents or other substances. They should, as a general rule, be performed in accordance with established guidelines⁽¹⁾ from recognized international Institutions although, because of the effects exerted at the cellular level by the proteinaceous nature and/or enzymatic activities of certain enzyme preparations, some modifications of the standard test protocols, particularly in the case of *in vitro* tests, may be necessary. Such deviations will be acceptable if accompanied by adequate supporting arguments.

The test system is designed to uncover unspecified toxic reactions and to reveal genotoxic effects. The combined information from the general specifications and this test battery make it possible to evaluate the product for the presence of both specific, well known toxins and unknown toxic compounds.

The toxicological report shall contain satisfactory documentation that the tests have been performed on the material which forms the basis of the commercial product as described in the technological dossier.

3.3. *Pharmacokinetics aspects*

If the active substance is chemically specified balance studies and identification of metabolites must be performed using suitable labelled molecules or other appropriate techniques and should cover both single and multiple dose administration of the active substance over appropriate periods. Metabolism studies must also include investigation of the pharmacokinetics of the active substance and of the major metabolites. Consideration must be given to the differences in the way that various species metabolize the active substance when selecting the most relevant species for subsequent toxicological investigations.

3.4. *Subchronic toxicity*

These studies must be carried out in general on two animal species (preferably the rat should be one). The second species may in some instances be a target species. The test substance may be administered orally and a dose-response relationship must be established. The duration in rodents must be at least 90 days.

In certain cases investigations extending over six months to two years in non-rodents may be desirable to establish the variation in sensitivity of different animal species to the test substance.

These studies are not relevant for microorganisms. In the case of enzyme preparations derived from microorganisms a 90-day oral toxicity test in a rodent species may be sufficient.

3.5. *Chronic toxicity/carcinogenicity*

Chronic toxicity studies must be carried out on one species (preferably the rat), carcinogenicity studies preferably on two species of rodent. The substance must be administered orally at several dose levels. A combined chronic toxicity/carcinogenicity study with *in-utero* exposure is also acceptable. Experiments must extend for a minimum of 24 months in rats and 18 months in mice. If continued beyond the minimum period, the test must be terminated when survival in any but the highest dose level groups has fallen to 20 %.

⁽¹⁾ Such as :

— Presentation of an application for assessment of a food additive prior to its authorization. 1989. (ISBN 92-826-0135-B)
— Report of the Scientific Committee for Food on guidelines for the safety assessment of food additives. 1980. 10th report series, (EUR 6892).

Full clinical chemistry, haematological and urine examinations must be carried out at appropriate intervals throughout the experiment. Full macroscopic and histological examinations must be carried out on all animals dying during the test and on all survivors at the termination of the study.

These studies are not relevant for microorganisms and enzyme preparations.

3.6. *Reproductive toxicity (where the active substance is chemically specified)*

Studies on reproduction must be carried out preferably on the rat. They must extend over at least two filial generations and may be combined with embryotoxicity including teratogenic studies. All relevant fertility, gestation, parturition, peri- and postnatal parameters must be carefully observed and reported. Specific teratogenic studies must be carried out in at least two suitable species.

3.7. *Toxicology of metabolites (where the active substance is chemically specified)*

Information for the calculation of residue concentration is required as a basis for assessing the risk for man.

The basis for calculation of the proposed withdrawal period must be made available. The studies mentioned in 1.3.4. must be carried out on laboratory animals.

3.8. *Other relevant studies*

Any further special study providing additional information useful for the assessment of test substance may be made available (e.g. bio-availability, neurotoxicity or immunotoxicity).

SECTION V

FORM OF MONOGRAPH

1. **Identity of the additive**

1.1. *Proposed proprietary name(s)*

1.2. *Type of additive according to its main function*

1.3. *Qualitative and quantitative composition (active substance, other components, impurities)*

1.4. *Physical state, particle size*

1.5. *Possible specific processing*

N.B. If the active substance is a mixture of active components, each of which is to be clearly definable, the main components must be described separately and the proportions in the mixture given.

2. **Specifications concerning the active substance**

2.1. For chemically specified substances : generic name, chemical name according to IUPAC nomenclature, other generic international names and abbreviations. Chemical Abstracts Service Number (CAS).

For microorganisms : name and taxonomic description according to the international Codes of Nomenclature. Other internationally recognized manuals of classification can also be used⁽¹⁾.

For enzyme preparations : name according to main enzymatic activities as described by IUB/Iupac, Einecs and CAS Number.

2.2. Formula, empirical and structural, and molecular weight. Qualitative and quantitative composition of the main components, if the active substance is a fermentation product.

For microorganisms : name and place of culture collection, if possible one in an EC collection, where the strain is deposited and depositing number, genetic modification and all relevant properties for its identification.

For enzyme preparations : the biological origin (in case of microbial origin : name and place of culture collection, if possible one in an EC collection, where the strain is deposited and depositing number, genetic modification and all relevant properties for its identification), the activities towards relevant chemically pure model substrates and other physico-chemical characteristics.

2.3. *Degree of purity*

Qualitative and quantitative composition of the impurities

For microorganisms : genetic stability and purity of strains cultivated.

For enzyme preparations :

— purity [by checking the level of contaminating microorganisms, heavy metals, absence of toxins (e.g. mycotoxins) derived from the source organism as shown by a suitable method];

⁽¹⁾ Such as *Bergey's Manual of Systematic Bacteriology*, *The Yeasts*, a taxonomic study by Lodder and Kreger van Rij, *Ainsworth and Bisby's Dictionary of the Fungi* by Hawksworth, Sutton and Ainsworth or *The Genus Aspergillus* by Raper and Fennell.

- absence of antimicrobial activity at feed concentration level as determined by a suitable method ;
- composition of the non-enzymatic components (particularly Total Organic Solids T.O.S.)

2.4. *Relevant properties*

For chemically specified substances : Electrostatic properties, melting point, boiling point, decomposition temperature, density, vapour pressure, solubility in water and organic solvents, mass and absorption spectra and any other appropriate physical properties.

For microorganisms : properties relevant to identification and proposed use (e.g. vegetative or sporulated form, CFU per g).

For enzyme preparations : optimal pH value(s), optimal temperature(s) and other appropriate properties.

3. **Physico-chemical, technological and biological properties of the additive**

- 3.1. Stability (for microorganisms : loss of biological activity, e.g. viability) on exposure to environmental conditions such as light, temperature, pH, moisture and oxygen. Shelf life.
- 3.2. Stability (for microorganisms : loss of biological activity, e.g. viability) during the preparation of premixtures and feedingstuffs, in particular stability to heat, pressure and moisture. Possible decomposition products.
- 3.3. Stability (for microorganisms : loss of biological activity, e.g. viability) during the storage of premixtures and feedingstuffs under defined conditions. Shelf life.
- 3.4. Other appropriate physico-chemical, technological or biological properties such as ability to obtain homogeneous mixtures in premixtures and feedingstuffs, dust-forming properties, and for microorganisms and/or enzyme preparations, assessment of resistance to degradation or loss of biological activity in the digestive tract or by systems of simulation *in vitro*.
- 3.5. Physico-chemical or biological incompatibilities or interactions (e.g. with feedingstuffs, other approved additives or with medicinal products).

4. **Control methods**

- 4.1. Description of the methods used for the determination of the criteria listed under items 1.3., 2.3., 2.4., 3.1., 3.2., 3.3. and 3.4. of this Section.
- 4.2. Description of the qualitative and quantitative analytical methods for determining residues of additives in animal produce.
- 4.3. If the said methods have been published the literature references may suffice and the corresponding reprints should be given.

5. **Biological properties of the additive**

- 5.1. Particulars of the prophylactic effects for coccidiostats and other medicinal substances (e.g. morbidity, oocyst count and lesion score).
- 5.2. For zootechnical additives other than those listed in 5.1. including if appropriate microorganisms and/or enzyme preparations : particulars of the effects on nutritional efficiency, animal growth, animal product characteristics and yield, animal welfare and other parameters having a positive influence on animal production.
- 5.3. Any contra-indications or warnings, including biological incompatibilities, with particulars of their justification.

6. **Details of the quantitative and qualitative residues, if any, found in animal produce following envisaged use of the additive.**

7. **Other characteristics suitable for identification of the additive.**

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 27 July 1994

approving the programme for the eradication of bovine tuberculosis presented by Ireland and fixing the level of the Community's financial contribution

(Only the English text is authentic)

(94/522/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to the Council Decision 90/424/EEC of 26 June on expenditure in the veterinary field⁽¹⁾, as last amended by Decision 94/370/EC⁽²⁾, and in particular Article 24, thereof,

Whereas Decision 90/424/EEC provides for the possibility of financial participation by the Community in the eradication and surveillance of bovine tuberculosis;

Whereas by letter dated 13 June 1994, Ireland has submitted a programme for the eradication of bovine tuberculosis;

Whereas after examination of the programme it was found to comply with all Community criteria relating to the eradication of the disease in conformity with Council Decision 90/638/EEC of 27 November 1990, on laying down Community criteria for the eradication and monitoring of certain animal diseases⁽³⁾, as last amended by Directive 92/65/EEC⁽⁴⁾;

Whereas in the light of the characteristics of implementation of tuberculosis eradication programmes in Ireland, it is appropriate to retain a flexible level of financial participation by the Community;

Whereas at the outset of the action, it is necessary to fix a level of Community funding which could be adjusted in the light of progress in the implementation of the programme, in particular reductions in the rate of animals from non-restricted herds showing lesions at slaughter and in the rate of disclosure of reactors, and also depending on the financial position of the Community budget;

Whereas this regime must constitute an incentive to assure the success of the programme;

Whereas the provisional level of funding at the outset of the programme should be fixed at 15 % guaranteed to the Irish authorities on completion of the programme;

Whereas in the light of the above, the definitive level of funding will be determined in January 1995;

Whereas a financial contribution from the Community shall be granted in so far as the actions provided for are carried out and provided that the authorities furnish all the necessary information within the time limits provided for;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

The programme for the eradication of bovine tuberculosis presented by the Ireland is hereby approved for the period from 1 July 1994 to 31 December 1994.

⁽¹⁾ OJ No L 224, 18. 8. 1990, p. 19.

⁽²⁾ OJ No L 168, 2. 7. 1994, p. 31.

⁽³⁾ OJ No L 347, 12. 12. 1990, p. 27.

⁽⁴⁾ OJ No L 268, 14. 9. 1992, p. 54.

Article 2

Ireland shall bring into force by 1 July 1994 the laws, regulations and administrative provisions for implementing the programme referred to in Article 1.

Article 3

1. The provisional financial participation by the Community shall be 15 % of the costs of testing incurred in Ireland up to a provisional maximum of ECU 2 500 000.

2. The Commission shall fix the definitive level of financial participation by the Community by 30 January 1995, on condition that the Irish authorities supply satisfactory evidence as to the success achieved before 15 January 1995. Where such evidence is not forthcoming, the level of Community financial participation could remain at 15 %. In any event, the maximum level of Community financial participation shall not be more than 50 % or ECU 8 700 000.

3. The financial contribution of the Community shall be granted to:

— forwarding a report to the Commission every three months on the progress of the programme and the costs incurred,

— forwarding a final report on the technical execution of the programme accompanied by justifying evidence as to the costs incurred by 1 July 1995 at the latest.

4. The financial contribution of the Community shall be paid in ECUs at the rate applying on the first working day of the month when the request of payment is made as published in the *Official Journal of the European Communities*.

Article 4

This Decision is addressed to Ireland.

Done at Brussels, 27 July 1994.

For the Commission

René STEICHEN

Member of the Commission

COMMISSION DECISION

of 27 July 1994

approving the programme for the eradication and surveillance of bovine brucellosis presented by France and fixing the level of the Community's financial contribution

(Only the French text is authentic)

(94/523/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to the Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ⁽¹⁾, as last amended by Decision 94/370/EC ⁽²⁾ and in particular Article 24, thereof,

Whereas Council Decision 90/424/EEC provides for the possibility of financial participation by the Community in the eradication and surveillance of bovine brucellosis;

Whereas by letter dated 17 June 1994, France has submitted a programme for the eradication of bovine brucellosis;

Whereas after examination of the programme it was found to comply with all Community criteria relating to the eradication of the disease in conformity with Council Decision 90/638/EEC on laying down Community criteria for the eradication and monitoring of certain animal diseases ⁽³⁾, as last amended by Council Directive 92/65/EEC ⁽⁴⁾;

Whereas in the light of the importance of the programme for the achievement of Community objectives in the field of animal health, it is appropriate to fix the financial participation of the Community at 50 % of the costs incurred by France up to a maximum of ECU 2 500 000;

Whereas a financial contribution from the Community shall be granted in so far as the actions provided for are carried out and provided that the authorities furnish all the necessary information within the time limits provided for;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

The programme of the eradication of bovine brucellosis presented by France is hereby approved for the period from 1 July 1994 to 31 December 1994.

Article 2

France shall bring into force by 1 July 1994 the laws, regulations and administrative provisions for implementing the programme referred to in Article 1.

Article 3

1. Financial participation by the Community shall be at the rate of 50 % of the costs of testing and those incurred in France by way of compensation for owners for the slaughter of animals up to a maximum of ECU 2 500 000.

2. The financial contribution of the Community shall be granted subject to:

— forwarding a report to the Commission every three months on the progress of the programme and the costs incurred,

— forwarding a final report on the technical execution of the programme accompanied by justifying evidence as the costs incurred by 1 July 1995 at the latest.

3. The financial contribution of the Community shall be paid in ecus at the rate applying on the first working day of the month when the request of payment is made as published in the *Official Journal of the European Communities*.

Article 4

This Decision is addressed to the French Republic.

Done at Brussels, 27 July 1994.

For the Commission

René STEICHEN

Member of the Commission

⁽¹⁾ OJ No L 224, 18. 8. 1990, p. 19.

⁽²⁾ OJ No L 168, 2. 7. 1994, p. 31.

⁽³⁾ OJ No L 347, 12. 12. 1990, p. 27.

⁽⁴⁾ OJ No L 268, 14. 9. 1992, p. 54.

COMMISSION DECISION

of 27 July 1994

approving the programme for the eradication and surveillance of bovine brucellosis presented by Ireland and fixing the level of the Community's financial contribution

(Only the English text is authentic)

(94/524/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to the Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ⁽¹⁾, as last amended by Decision 94/370/EC ⁽²⁾ and in particular Article 24, thereof,

Whereas Council Decision 90/424/EEC provides for the possibility of financial participation by the Community in the eradication and surveillance of bovine brucellosis;

Whereas by letter dated 20 May 1994, Ireland has submitted a programme for the eradication of bovine brucellosis;

Whereas after examination of the programme it was found to comply with all Community criteria relating to the eradication of the disease in conformity with Council Decision 90/638/EEC on laying down Community criteria for the eradication and monitoring of certain animal diseases ⁽³⁾, as last amended by Council Directive 92/65/EEC ⁽⁴⁾;

Whereas in the light of the importance of the programme for the achievement of Community objectives in the field of animal health, it is appropriate to fix the financial participation of the Community at 50 % of the costs incurred by Ireland up to a maximum of ECU 2 450 000;

Whereas a financial contribution from the Community shall be granted in so far as the actions provided for are carried out and provided that the authorities furnish all the necessary information within the time limits provided for;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

The programme of the eradication of bovine brucellosis presented by Ireland is hereby approved for the period from 1 July 1994 to 31 December 1994.

Article 2

Ireland shall bring into force by 1 July 1994 the laws, regulations and administrative provisions for implementing the programme referred to in Article 1.

Article 3

1. Financial participation by the Community shall be at the rate of 50 % of the costs of testing and those incurred in Ireland by way of compensation for owners for the slaughter of animals up to a maximum of ECU 2 450 000.

2. The financial contribution of the Community shall be granted subject to:

- forwarding a report to the Commission every three months on the progress of the programme and the costs incurred,
- forwarding a final report on the technical execution of the programme accompanied by justifying evidence as the costs incurred by 1 July 1995 at the latest.

3. The financial contribution of the Community shall be paid in ecus at the rate applying on the first working day of the month when the request of payment is made as published in the *Official Journal of the European Communities*.

Article 4

This Decision is addressed to Ireland.

Done at Brussels, 27 July 1994.

For the Commission

René STEICHEN

Member of the Commission

⁽¹⁾ OJ No L 224, 18. 8. 1990, p. 19.

⁽²⁾ OJ No L 168, 2. 7. 1994, p. 31.

⁽³⁾ OJ No L 347, 12. 12. 1990, p. 27.

⁽⁴⁾ OJ No L 268, 14. 9. 1992, p. 54.

COMMISSION DECISION

of 27 July 1994

approving the programme for the eradication and surveillance of bovine brucellosis presented by Spain and fixing the level of the Community's financial contribution

(Only the Spanish text is authentic)

(94/525/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to the Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ⁽¹⁾, as last amended by Decision 94/370/EC ⁽²⁾ and in particular Article 24, thereof,

Whereas Council Decision 90/424/EEC provides for the possibility of financial participation by the Community in the eradication and surveillance of bovine brucellosis;

Whereas by letter dated 8 June 1994, Spain has submitted a programme for the eradication of bovine brucellosis;

Whereas after examination of the programme it was found to comply with all Community criteria relating to the eradication of the disease in conformity with Council Decision 90/638/EEC on laying down Community criteria for the eradication and monitoring of certain animal diseases ⁽³⁾, as last amended by Council Directive 92/65/EEC ⁽⁴⁾;

Whereas in the light of the importance of the programme for the achievement of Community objectives in the field of animal health, it is appropriate to fix the financial participation of the Community at 50 % of the costs incurred by Spain up to a maximum of ECU 4 600 000;

Whereas a financial contribution from the Community shall be granted in so far as the actions provided for are carried out and provided that the authorities furnish all the necessary information within the time limits provided for;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

The programme of the eradication of bovine brucellosis presented by Spain is hereby approved for the period from 1 July 1994 to 31 December 1994.

Article 2

Spain shall bring into force by 1 July 1994 the laws, regulations and administrative provisions for implementing the programme referred to in Article 1.

Article 3

1. Financial participation by the Community shall be at the rate of 50 % of the costs of testing and those incurred in Spain by way of compensation for owners for the slaughter of animals up to a maximum of ECU 4 600 000.

2. The financial contribution of the Community shall be granted subject to:

- forwarding a report to the Commission every three months on the progress of the programme and the costs incurred,
- forwarding a final report on the technical execution of the programme accompanied by justifying evidence as the costs incurred by 1 July 1995 at the latest.

3. The financial contribution of the Community shall be paid in ecus at the rate applying on the first working day of the month when the request of payment is made as published in the *Official Journal of the European Communities*.

Article 4

This Decision is addressed to the Kingdom of Spain.

Done at Brussels, 27 July 1994.

For the Commission

René STEICHEN

Member of the Commission

⁽¹⁾ OJ No L 224, 18. 8. 1990, p. 19.

⁽²⁾ OJ No L 168, 2. 7. 1994, p. 31.

⁽³⁾ OJ No L 347, 12. 12. 1990, p. 27.

⁽⁴⁾ OJ No L 268, 14. 9. 1992, p. 54.

COMMISSION DECISION**of 27 July 1994****approving the programme for the eradication and surveillance of bovine
brucellosis presented by Portugal and fixing the level of the Community's
financial contribution****(Only the Portuguese text is authentic)****(94/526/EC)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to the Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ⁽¹⁾, as last amended by Decision 94/370/EC ⁽²⁾ and in particular Article 24, thereof,

Whereas Council Decision 90/424/EEC provides for the possibility of financial participation by the Community in the eradication and surveillance of bovine brucellosis;

Whereas by letter dated 6 May 1994, Portugal has submitted a programme for the eradication of bovine brucellosis which replaces the programme currently in force in Portugal, approved by Commission Decision 92/301/EEC ⁽³⁾;

Whereas after examination of the programme it was found to comply with all Community criteria relating to the eradication of the disease in conformity with Council Decision 90/638/EEC on laying down Community criteria for the eradication and monitoring of certain animal diseases ⁽⁴⁾, as last amended by Council Directive 92/65/EEC ⁽⁵⁾;

Whereas it is necessary to delete Decision 92/301/EEC;

Whereas in the light of the importance of the programme for the achievement of Community objectives in the field of animal health, it is appropriate to fix the financial participation of the Community at 50 % of the costs incurred by Portugal up to a maximum of ECU 1 440 000;

Whereas a financial contribution from the Community shall be granted in so far as the actions provided for are

carried out and provided that the authorities furnish all the necessary information within the time limits provided for;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

The programme of the eradication of bovine brucellosis presented by Portugal is hereby approved for the period from 1 July 1994 to 31 December 1994.

Article 2

Portugal shall bring into force by 1 July 1994 the laws, regulations and administrative provisions for implementing the programme referred to in Article 1.

Article 3

Decision 92/301/EEC is hereby repealed.

Article 4

1. Financial participation by the Community shall be at the rate of 50 % of the costs of testing and those incurred in Portugal by way of compensation for owners for the slaughter of animals up to a maximum of ECU 1 440 000.

2. The financial contribution of the Community shall be granted subject to:

- forwarding a report to the Commission every three months on the progress of the programme and the costs incurred,
- forwarding a final report on the technical execution of the programme accompanied by justifying evidence as the costs incurred by 1 July 1995 at the latest.

⁽¹⁾ OJ No L 224, 18. 8. 1990, p. 19.

⁽²⁾ OJ No L 168, 2. 7. 1994, p. 31.

⁽³⁾ OJ No L 162, 16. 6. 1992, p. 20.

⁽⁴⁾ OJ No L 347, 12. 12. 1990, p. 27.

⁽⁵⁾ OJ No L 268, 14. 9. 1992, p. 54.

3. The financial contribution of the Community shall be paid in ecus at the rate applying on the first working day of the month when the request of payment is made as published in the *Official Journal of the European Communities*.

Article 5

This Decision is addressed to the Portuguese Republic.

Done at Brussels, 27 July 1994.

For the Commission

René STEICHEN

Member of the Commission

CORRIGENDA

Corrigendum to Council Regulation (EC) No 1800/94 of 18 July 1994 opening and providing for the administration of Community tariff quotas for bulls, cows and heifers, other than those intended for slaughter, of certain Alpine and mountain breeds

(Official Journal of the European Communities No L 189 of 23 July 1994)

On page 21 the table in Article 1 (1) shall be replaced by the following :

'Order No	CN code (¹)	Designation	Quota volume	Quota duty (%)
09.0001	ex 0102 90 05 ex 0102 90 29 ex 0102 90 49 ex 0102 90 59 ex 0102 90 69	Cows and heifers other than those intended for slaughter (a) of the following mountain breeds: grey, brown, yellow and mottled Simmental breed and mottled Pintzgau breed	21 300 head from 1. 7. 1994 to 31. 12. 1994	4 %
			10 000 head from 1. 1. 1995 to 30. 6. 1995 (b)	6 %
09.0003	ex 0102 90 05 ex 0102 90 29 ex 0102 90 49 ex 0102 90 59 ex 0102 90 69 ex 0102 90 79	Bulls, cows and heifers other than those intended for slaughter (a) of the following breeds: mottled Simmental breed and the Schwyz and Fribourg breeds	5 000 head from 1. 7. 1994 to 30. 6. 1995	4 %

(¹) Taric codes in Annex I.

(a) The control of this particular end-use is carried out by application of the relevant Community provisions.

(b) The Community reserves the right to adapt this quantity as a consequence of enlargement.'

Corrigendum to Commission Regulation (EC) No 1640/94 of 6 July 1994 determining for the Member States, for the 1993 marketing year, the estimated loss of income and the estimated loss of income and the estimated level of the premium payable per ewe and per female goat and fixing the first advance payment for this premium and an advance payment of the specific aid for sheep and goat farming in certain less favoured areas of the Community

(Official Journal of the European Communities No L 172 of 7 July 1994)

On page 10 in the title :

for: '... for the 1993 marketing year, ...',

read: '... for the 1994 marketing year, ...'.