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**COUNCIL DIRECTIVE**  
**of 23 November 1970**  
**concerning additives in feeding-stuffs**  
**(70/524/EEC)**

(OJ L 270, 14.12.1970, p. 1)

Amended by:

		Official Journal		
		No	page	date
► <b><u>M1</u></b>	Council Directive of 28 April 1973 (73/103/EEC)	L 124	17	10.5.1973
► <b><u>M2</u></b>	First Commission Directive of 27 July 1973 (73/264/EEC)	L 253	12	10.9.1973
► <b><u>M3</u></b>	Second Commission Directive of 27 July 1973 (73/275/EEC)	L 254	16	11.9.1973
► <b><u>M4</u></b>	Third Commission Directive of 13 December 1973 (74/7/EEC)	L 14	21	17.1.1974
► <b><u>M5</u></b>	Fourth Commission Directive of 17 December 1973 (74/38/EEC)	L 30	21	4.2.1974
► <b><u>M6</u></b>	Fifth Commission Directive of 26 February 1974 (74/180/EEC)	L 94	14	4.4.1974
► <b><u>M7</u></b>	Sixth Commission Directive of 26 February 1974 (74/181/EEC)	L 94	16	4.4.1974
► <b><u>M8</u></b>	Seventh Commission Directive of 26 February 1974 (74/182/EEC)	L 94	18	4.4.1974
► <b><u>M9</u></b>	Eighth Commission Directive of 1 July 1974 (74/378/EEC)	L 199	13	22.7.1974
► <b><u>M10</u></b>	Ninth Commission Directive of 23 July 1974 (74/421/EEC)	L 221	29	12.8.1974
► <b><u>M11</u></b>	Tenth Commission Directive of 20 December 1974 (75/50/EEC)	L 19	58	24.1.1975
► <b><u>M12</u></b>	Eleventh Commission Directive of 24 April 1975 (75/267/EEC)	L 118	45	8.5.1975
► <b><u>M13</u></b>	Second Council Directive of 28 April 1975 (75/296/EEC)	L 124	29	15.5.1975
► <b><u>M14</u></b>	Twelfth Commission Directive of 24 October 1975 (75/696/EEC)	L 299	19	19.11.1975
► <b><u>M15</u></b>	Thirteenth Commission Directive of 15 December 1975 (76/13/EEC)	L 4	21	9.1.1976
► <b><u>M16</u></b>	Fourteenth Commission Directive of 8 June 1976 (76/546/EEC)	L 160	11	22.6.1976
► <b><u>M17</u></b>	Fifteenth Commission Directive of 21 June 1976 (76/603/EEC)	L 198	10	23.7.1976
► <b><u>M18</u></b>	Sixteenth Commission Directive of 1 December 1976 (76/933/EEC)	L 364	18	31.12.1976
► <b><u>M19</u></b>	Seventeenth Commission Directive of 16 February 1977 (77/179/EEC)	L 60	15	5.3.1977
► <b><u>M20</u></b>	Eighteenth Commission Directive of 11 July 1977 (77/471/EEC)	L 180	27	20.7.1977
► <b><u>M21</u></b>	Nineteenth Commission Directive of 26 July 1977 (77/512/EEC)	L 207	53	13.8.1977
► <b><u>M22</u></b>	20th Commission Directive of 7 December 1977 (78/58/EEC)	L 18	7	24.1.1978
► <b><u>M23</u></b>	Twenty-first Commission Directive of 23 December 1977 (78/117/EEC)	L 40	19	10.2.1978
► <b><u>M24</u></b>	Twenty-second Commission Directive of 30 May 1978 (78/522/EEC)	L 159	43	17.6.1978
► <b><u>M25</u></b>	Twenty-third Commission Directive of 23 June 1978 (78/613/EEC)	L 198	10	22.7.1978
► <b><u>M26</u></b>	Twenty-fourth Commission Directive of 28 July 1978 (78/743/EEC)	L 247	25	9.9.1978
► <b><u>M27</u></b>	Twenty-fifth Commission Directive of 16 November 1978 (78/974/EEC)	L 330	30	25.11.1978
► <b><u>M28</u></b>	Twenty-sixth Commission Directive of 18 December 1978 (79/139/EEC)	L 39	11	14.2.1979

► <b><u>M29</u></b>	Twenty-seventh Commission Directive of 7 June 1979 (79/553/EEC)	L 148	58	16.6.1979
► <b><u>M30</u></b>	Twenty-eighth Commission Directive of 20 July 1979 (79/697/EEC)	L 207	19	15.8.1979
► <b><u>M31</u></b>	Twenty-ninth Commission Directive of 15 November 1979 (79/1011/EEC)	L 310	24	6.12.1979
► <b><u>M32</u></b>	Thirtieth Commission Directive of 9 January 1980 (80/131/EEC)	L 30	21	7.2.1980
► <b><u>M33</u></b>	Thirty-first Commission Directive of 8 April 1980 (80/440/EEC)	L 104	18	22.4.1980
► <b><u>M34</u></b>	Thirty-second Commission Directive of 26 June 1980 (80/618/EEC)	L 171	36	4.7.1980
► <b><u>M35</u></b>	Thirty-third Commission Directive of 4 July 1980 (80/678/EEC)	L 185	48	18.7.1980
► <b><u>M36</u></b>	Thirty-fourth Commission Directive of 4 September 1980 (80/884/EEC)	L 251	17	24.9.1980
► <b><u>M37</u></b>	Thirty-fifth Commission Directive of 25 November 1980 (80/1139/EEC)	L 336	42	13.12.1980
► <b><u>M38</u></b>	Thirty-sixth Commission Directive of 28 November 1980 (80/1156/EEC)	L 343	35	18.12.1980
► <b><u>M39</u></b>	Thirty-seventh Commission Directive of 9 April 1981 (81/332/EEC)	L 131	1	18.5.1981
► <b><u>M40</u></b>	Thirty-eighth Commission Directive of 16 July 1981 (81/632/EEC)	L 231	30	15.8.1981
► <b><u>M41</u></b>	Thirty-ninth Commission Directive of 15 January 1982 (82/91/EEC)	L 42	16	13.2.1982
► <b><u>M42</u></b>	Council Directive of 30 June 1982 (82/471/EEC)	L 213	8	21.7.1982
► <b><u>M43</u></b>	Fortieth Commission Directive of 23 June 1982 (82/474/EEC)	L 213	22	21.7.1982
► <b><u>M44</u></b>	Forty-first Commission Directive of 19 November 1982 (82/822/EEC)	L 347	16	7.12.1982
► <b><u>M45</u></b>	Forty-second Commission Directive of 16 May 1983 (83/266/EEC)	L 147	18	6.6.1983
► <b><u>M46</u></b>	Forty-third Commission Directive of 28 July 1983 (83/466/EEC)	L 255	28	15.9.1983
► <b><u>M47</u></b>	Forty-fourth Commission Directive of 29 November 1983 (83/615/EEC)	L 350	17	13.12.1983
► <b><u>M48</u></b>	Forty-fifth Commission Directive of 15 February 1984 (84/107/EEC)	L 61	35	2.3.1984
► <b><u>M49</u></b>	Forty-sixth Commission Directive of 28 May 1984 (84/349/EEC)	L 183	15	11.7.1984
► <b><u>M50</u></b>	Forty-seventh Commission Directive of 26 October 1984 (84/547/EEC)	L 297	40	15.11.1984
► <b><u>M51</u></b>	Council Directive of 29 November 1984 (84/587/EEC)	L 319	13	8.12.1984
► <b><u>M52</u></b>	Forty-eighth Commission Directive of 6 February 1985 (85/157/EEC)	L 59	27	27.2.1985
► <b><u>M53</u></b>	Forty-ninth Commission Directive of 31 May 1985 (85/312/EEC)	L 165	21	25.6.1985
► <b><u>M54</u></b>	Fiftieth Commission Directive of 24 June 1985 (85/342/EEC)	L 179	35	11.7.1985
► <b><u>M55</u></b>	Commission Directive of 8 July 1985 (85/429/EEC)	L 245	1	12.9.1985
► <b><u>M56</u></b>	Commission Directive of 11 November 1985 (85/520/EEC)	L 323	12	4.12.1985
► <b><u>M57</u></b>	Council Regulation (EEC) No 3768/85 of 20 December 1985	L 362	8	31.12.1985
► <b><u>M58</u></b>	Second Commission Directive of 5 February 1986 (86/29/EEC)	L 39	55	14.2.1986
► <b><u>M59</u></b>	Commission Directive of 4 June 1986 (86/300/EEC)	L 189	42	11.7.1986
► <b><u>M60</u></b>	Commission Directive of 28 July 1986 (86/403/EEC)	L 233	16	20.8.1986
► <b><u>M61</u></b>	Commission Directive of 27 October 1986 (86/525/EEC)	L 310	19	5.11.1986
► <b><u>M62</u></b>	Commission Directive of 23 April 1987 (87/243/EEC)	L 110	34	25.4.1987
► <b><u>M63</u></b>	Commission Directive of 23 April 1987 (87/244/EEC)	L 110	35	25.4.1987
► <b><u>M64</u></b>	Council Directive of 16 June 1987 (87/316/EEC)	L 160	32	20.6.1987
► <b><u>M65</u></b>	Council Directive of 16 June 1987 (87/317/EEC)	L 160	34	20.6.1987
► <b><u>M66</u></b>	Commission Directive of 17 November 1987 (87/552/EEC)	L 336	34	26.11.1987
► <b><u>M67</u></b>	Commission Directive of 8 April 1988 (88/228/EEC)	L 101	30	20.4.1988
► <b><u>M68</u></b>	Commission Directive of 14 July 1988 (88/483/EEC)	L 237	39	27.8.1988
► <b><u>M69</u></b>	Commission Directive of 30 November 1988 (88/616/EEC)	L 343	25	13.12.1988

▶ <b>M70</b>	Commission Directive of 21 December 1988 (89/23/EEC)	L 11	34	14.1.1989
▶ <b>M71</b>	Commission Directive of 27 October 1989 (89/583/CEE)	L 325	33	10.11.1989
▶ <b>M72</b>	Commission Directive of 19 February 1990 (90/110/EEC)	L 67	44	15.3.1990
▶ <b>M73</b>	Commission Directive of 9 April 1990 (90/206/EEC)	L 106	30	26.4.1990
▶ <b>M74</b>	Commission Directive of 20 April 1990 (90/214/EEC)	L 113	39	4.5.1990
▶ <b>M75</b>	Commission Directive of 20 July 1990 (90/412/EEC)	L 209	25	8.8.1990
▶ <b>M76</b>	Commission Directive of 26 November 1990 (90/643/EEC)	L 350	80	14.12.1990
▶ <b>M77</b>	Council Directive of 4 December 1990 (90/654/EEC)	L 353	48	17.12.1990
▶ <b>M78</b>	Commission Directive of 12 April 1991 (91/248/EEC)	L 124	1	18.5.1991
▶ <b>M79</b>	Commission Directive of 19 April 1991 (91/249/EEC)	L 124	43	18.5.1991
▶ <b>M80</b>	Commission Directive of 10 June 1991 (91/336/EEC)	L 185	31	11.7.1991
▶ <b>M81</b>	Commission Directive of 9 September 1991 (91/508/EEC)	L 271	67	27.9.1991
▶ <b>M82</b>	Commission Directive of 22 November 1991 (91/620/EEC)	L 334	62	5.12.1991
▶ <b>M83</b>	Commission Directive 92/64/EEC of 13 July 1992	L 221	51	6.8.1992
▶ <b>M84</b>	Commission Directive 92/99/EEC of 17 November 1992	L 350	83	1.12.1992
▶ <b>M85</b>	Commission Directive 92/113/EEC of 16 December 1992	L 16	2	25.1.1993
▶ <b>M86</b>	Commission Directive 93/27/EEC of 4 June 1993	L 179	5	22.7.1993
▶ <b>M87</b>	Commission Directive 93/55/EEC of 25 June 1993	L 206	11	18.8.1993
▶ <b>M88</b>	Commission Directive 93/107/EC of 26 November 1993	L 299	44	4.12.1993
▶ <b>M89</b>	Council Directive 93/114/EC of 14 December 1993	L 334	24	31.12.1993
▶ <b>M90</b>	Commission Directive 94/17/EC of 22 April 1994	L 105	19	26.4.1994
▶ <b>M91</b>	Commission Directive of 18 July 1994 (94/41/CE)	L 209	18	12.8.1994
▶ <b>M92</b>	Commission Directive 94/50/EC of 31 October 1994	L 297	27	18.11.1994
▶ <b>M93</b>	Commission Directive 94/77/EC of 20 December 1994	L 350	113	31.12.1994
▶ <b>M94</b>	Commission Directive 95/37/EC of 18 July 1995	L 172	21	22.7.1995
▶ <b>M95</b>	Commission Directive 95/55/EC of 31 October 1995	L 263	18	4.11.1995
▶ <b>M96</b>	Council Directive 95/69/EC of 22 December 1995	L 332	15	30.12.1995
▶ <b>M97</b>	Commission Directive 96/7/EC of 21 February 1996	L 51	45	1.3.1996
▶ <b>M98</b>	▶ <b>M99</b> Council Directive 96/25/EC of 29 April 1996 ◀	L 125	35	23.5.1996
▶ <b>M99</b>	amended by Directive 2000/16/EC of the European Parliament and the Council of 10 April 2000	L 105	36	3.5.2000
▶ <b>M100</b>	Council Directive 96/51/EC of 23 July 1996	L 235	39	17.9.1996
▶ <b>M101</b>	Commission Directive 96/66/EC of 14 October 1996	L 272	32	25.10.1996
▶ <b>M102</b>	Commission Directive 97/6/EC of 30 January 1997	L 35	11	5.2.1997
▶ <b>M103</b>	Commission Directive 97/72/EC of 15 December 1997	L 351	55	23.12.1997
▶ <b>M104</b>	Commission Directive 98/19/EC of 18 March 1998	L 96	39	28.3.1998
▶ <b>M105</b>	Commission Regulation (EC) No 2786/98 of 22 December 1998	L 347	25	23.12.1998
▶ <b>M106</b>	Council Directive 98/92/EC of 14 December 1998	L 346	49	22.12.1998
▶ <b>M107</b>	Commission Regulation (EC) No 2788/98 of 22 December 1998	L 347	31	23.12.1998
▶ <b>M108</b>	Council Regulation (EC) No 2821/98 of 17 December 1998	L 351	4	29.12.1998
▶ <b>M109</b>	Council Directive 1999/20/EC of 22 March 1999	L 80	20	25.3.1999
▶ <b>M110</b>	Commission Regulation (EC) No 45/1999 of 11 January 1999	L 6	3	12.1.1999
▶ <b>M111</b>	Directive 2001/46/EC of the European Parliament and of the Council of 23 July 2001	L 234	55	1.9.2001

Amended by:

▶ <u>A1</u>	Act of Accession of Greece	L 291	17	19.11.1979
▶ <u>A2</u>	Act of Accession of Spain and Portugal	L 302	23	15.11.1985
▶ <u>A3</u>	Act of Accession of Austria, Sweden and Finland	C 241	21	29.8.1994
	(adapted by Council Decision 95/1/EC, Euratom, ECSC)	L 1	1	1.1.1995

Corrected by:

- ▶ C1 Consolidated text of corrigenda to instruments published in Special Editions 1952-72, p. 80 (70/524/EEC)
- ▶ C2 Corrigendum, OJ L 320, 27.11.1980, p. 43 (80/678/EEC)
- ▶ C3 Corrigendum, OJ L 237, 12.8.1982, p. 46 (82/474/EEC)
- ▶ C4 Corrigendum, OJ L 83, 30.3.1990, p. 128 (90/110/EEC)
- ▶ C5 Corrigendum, OJ L 96, 12.4.1990, p. 92 (90/110/EEC)
- ▶ C6 Corrigendum, OJ L 174, 3.7.1991, p. 38 (91/249/EEC)
- ▶ C7 Corrigendum, OJ L 287, 17.10.1991, p. 44 (91/248/EEC)
- ▶ C8 Corrigendum, OJ L 44, 17.2.1994, p. 35 (93/114/EC)
- ▶ C9 Corrigendum, OJ L 115, 16.5.2000, p. 22 (96/51/EC)

▼B

**COUNCIL DIRECTIVE**  
**of 23 November 1970**  
**concerning additives in feeding-stuffs**  
(70/524/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 43 and 100 thereof;

Having regard to the proposal from the Commission;

Having regard to the Opinion of the European Parliament <sup>(1)</sup>;

Having regard to the Opinion of the Economic and Social Committee;

Whereas livestock production occupies a very important place in the agriculture of the European Economic Community; whereas satisfactory results depend to a large extent on the use of appropriate good-quality feeding-stuffs;

Whereas the existence of rules concerning feeding-stuffs is essential to an increase in agricultural productivity;

Whereas animal feeding increasingly involves the use of additives;

Whereas the provisions laid down in the Member States by law, regulation or administrative action concerning additives in feeding-stuffs, insofar as they exist, differ as regards their basic principles; whereas it follows that they directly affect the establishment and functioning of the common market and should therefore be harmonised;

Whereas, as a general rule, 'additives' means substances which improve both the feeding-stuffs in which they are incorporated and livestock production; whereas, for this reason, antibiotics should also be regarded as additives since, when used in small quantities, they have a physiological nutritional effect, although when used in large quantities they have a medicinal effect;

Whereas these substances must not be used in feeding-stuffs for the prime purpose of diagnosing, treating or preventing disease; whereas they should, however be authorised for the sole purpose of improving feeding-stuffs by preventing nutritional deficiencies;

Whereas, furthermore, certain purely medicinal substances such as coccidiostats should, during a first stage, be regarded in relation to feeding-stuffs as additives, since most Member States have been using them for collective prophylaxis, principally in poultry-farming; whereas, however, they will be examined further if a directive on medicinal feeding-stuffs is drawn up;

Whereas the basic principle underlying rules in this field must be that only those additives which are named in this Directive may be contained in feeding-stuffs and only subject to the requirements set out herein, and that such additives may not, subject to the exceptions provided for, be used in any other way for the purposes of animal feeding;

Whereas it is necessary, at the time when additives are authorised, to make sure that they have a favourable effect on the characteristics of the feeding-stuffs to which they are added or on livestock production; whereas they must not endanger animal or human health nor harm the consumer of livestock products; whereas, subject to the exceptions provided for, it is advisable to examine whether such additives may now be used for the treatment or prevention of disease or whether there are still serious reasons for restricting their use to medical or veterinary purposes;

<sup>(1)</sup> OJ No C 135, 14.12.1968, p. 20.

**▼B**

Whereas, because of the special situation of certain Member States, and in particular because of their different systems of animal feeding, it is necessary in certain cases to allow derogations from the above-mentioned principles to an extent acceptable for animal and human health;

Whereas Member States should also retain the power to suspend the use of certain additives or to lower their maximum levels if animal or human health is being endangered; whereas Member States should not, however, be able to have recourse to that power in order to hinder the free movement of the various products;

Whereas provision should be made for feeding-stuffs containing additives to be specially labelled so that the user may know the nature of the additive and be protected against fraud; whereas this provision refers particularly to ►C1 supplementary ◀ feeding-stuffs containing concentrates of certain additives;

Whereas Community rules should not apply to feeding-stuffs intended for export to third countries, as the latter generally apply different rules;

Whereas, in order to ensure that the requirements laid down in respect of additives are satisfied during marketing, Member States must make provision for appropriate control arrangements;

Whereas feeding-stuffs satisfying these requirements must be subject only to the marketing restrictions provided for in this Directive;

Whereas, in order to facilitate implementation of this Directive, a procedure should be applied which establishes close co-operation between Member States and the Commission within the Standing Committee for Feeding-stuffs;

HAS ADOPTED THIS DIRECTIVE:

**▼M100**

## SCOPE

*Article 1*

1. This Directive shall apply to additives in feedingstuffs.
2. This Directive shall not apply to processing aids used deliberately as substances in the processing of feed materials or of feedingstuffs in order to achieve a certain technological objective during treatment or processing which may result in the unintentional but technically unavoidable presence of residues of the substances or their derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product.
3. Provided they are not products specially enriched with substances corresponding to additives, substances present in their natural state in feed materials which are part of the normal composition of feeding-stuffs and which correspond to a substance authorized under this Directive shall not be regarded as additives.

## DEFINITIONS

**▼M51***Article 2*

For the purposes of this Directive the following definitions shall apply:

**▼M100**

- (a) *Additives*: substances or preparations used in animal nutrition in order to:
  - affect favourably the characteristics of feed materials or of compound feedingstuffs or of animal products; or

**▼ M100**

- satisfy the nutritional needs of animals or improve animal production, in particular by affecting the gastrointestinal flora or the digestibility of feedingstuffs; or
  - introduce into nutrition elements conducive to attaining particular nutritional objectives or to meeting the specific nutritional needs of animals at a particular time; or
  - prevent or reduce the harmful effects caused by animal excretions or improve the animal environment;
- (aa) *Micro-organisms*: micro-organisms forming colonies;
- (aaa) additives subject to authorization linked to the person responsible for putting them into circulation: the additives listed in Part I of Annex C;
- (aaaa) *Other additives*: additives not subject to authorization linked to the person responsible for putting them into circulation and referred to in Part II of Annex C;

**▼ M51**

- (b) *Feedingstuffs*: products of vegetable or animal origin in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, used singly or in mixtures, whether or not containing additives, for oral animal feeding;
- (c) *Daily ration*: the average total quantity of feedingstuffs, calculated on a moisture content of 12 %, required daily by an animal of a given species, age category and yield, to satisfy all its needs;
- (d) *Complete feedingstuffs*: mixtures of feedingstuffs which, by reason of their composition, are sufficient for a daily ration;
- (e) *Supplementary feedingstuffs*: mixtures of feedingstuffs which have a high content of certain substances and which, by reason of their composition, are sufficient for a daily ration only if they are used in combination with other feedingstuffs;

**▼ M100**

- (f) *Feed materials*: various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding either directly as such or after processing, in the preparation of compound feedingstuffs or as carriers of premixtures, hereinafter referred to as *feed materials*;

**▼ M98**

- (g) *Compound feedingstuffs*: mixtures of feed materials, whether or not containing additives, which are intended for oral animal feeding as complete or complementary feedingstuffs;

**▼ M51**

- (h) *Premixtures*: mixtures of additives or mixtures of one or more additives with substances used as carriers, intended for the manufacture of feedingstuffs;
- (i) *Animals*: animals belonging to species normally nourished and kept or consumed by man;
- (j) *Pet animals*: animals belonging to species normally nourished and kept, but not consumed, by man, except animals bred for fur;

**▼ M111**

- (k) *Putting into circulation or circulation*: the holding of any product intended for animal nutrition for the purposes of sale, including offering for sale, or any other form of transfer, whether free or not, to third parties, and the sale and other forms of transfer themselves;

**▼ M100**

- (l) *Person responsible for putting into circulation*: the natural or legal person who has responsibility for the conformity of the additive which has been granted Community authorization and for putting it into circulation.

▼ **M100**

## PROCEDURE FOR THE AUTHORIZATION OF ADDITIVES

*Article 3*

Member States shall require that no additive may be put into circulation unless a Community authorization has been granted. This authorization shall be granted under a Commission regulation in accordance with the procedure laid down in Article 4.

*Article 3a*

Community authorization of an additive shall be given only if:

- (a) when used in animal nutrition it has one of the effects referred to in Article 2 (a);
- (b) taking account of the conditions of use, it does not adversely affect human or animal health or the environment, nor harm the consumer by impairing the characteristics of animal products;
- (c) its presence can be monitored:
  - as an additive per se,
  - in premixtures,
  - in feedingstuffs or, where appropriate, in feed materials;
- (d) at the level permitted, treatment or prevention of animal disease is excluded; this condition shall not apply to additives belonging to the group of coccidiostats and other medicinal substances;
- (e) for serious reasons concerning human or animal health its use must not be restricted to medical or veterinary purposes.

*Article 4*

1. In order to obtain the Community authorization for a substance or a preparation as an additive or for a new use in the case of an already authorized additive, the applicant for authorization shall select a Member State to act as rapporteur during the scrutiny procedure on the dossier he has compiled in accordance with the provisions of Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition<sup>(1)</sup>. Where the applicant is established in a third country, he must have a representative in the Community.

2. The Member State acting as rapporteur shall check that:

- (a) the dossier has been compiled in accordance with Directive 87/153/EEC;
- (b) the substance or preparation, according to the information given, appears to meet the conditions laid down in Article 3a.

3. The applicant for Community authorization shall dispatch to the Commission, via the Member State acting as rapporteur, an application accompanied by the dossier, sending copies to the other Member States, which shall acknowledge receipt at the earliest opportunity. That dispatch shall be affected no later than one year after the date of submission of the applicant's dossier in the Member State acting as rapporteur, unless the latter is rejected or postponed. The Member State acting as rapporteur shall inform the applicant, the other Member States and the Commission of the reasons for rejection or postponement of the dossier.

4. Member States shall have a period of sixty days from the date on which the dossier was dispatched to them in which to check whether the dossier has been compiled in accordance with Directive 87/153/EEC and, where appropriate, to submit their comments in writing to the Commission and the other Member States.

<sup>(1)</sup> OJ No L 64, 7. 3. 1987, p. 19. Directive as last amended by Directive 95/11/EC (OJ No L 106, 11. 5. 1995, p. 23).



**▼M100**

If, on expiry of the period referred to in the first paragraph, no objection has been made, the representative of the Commission shall have a period of thirty days in which to include the authorization application on the agenda for the Standing Committee for Feedingstuffs.

5. If, after consultation of the Standing Committee for Feedingstuffs, it is deemed that the rules on presentation of dossiers have not been complied with, a representative of the Commission shall so notify the applicant for authorization to put into circulation and the Member State acting as rapporteur; where necessary, a new application must be submitted in accordance with the above provisions.

6. The Commission shall ensure that a decision is taken, in accordance with the procedure laid down in Article 23, on the application for Community authorization within 320 days following its inclusion on the agenda for the Standing Committee for Feedingstuffs in accordance with the second subparagraph of paragraph 4. However, this time limit shall be interrupted where a request is made for additional information by a Member State in the Standing Committee for Feedingstuffs, or at the request of the Scientific Committee for Animal Nutrition.

Where an application for Community authorization to put an additive into circulation is rejected or the decision on it is postponed, a representative of the Commission shall inform the applicant for authorization and the Member State acting as rapporteur of the reasons for the rejection or postponement of the decision.

*Article 5*

Amendments to Directive 87/153/EEC:

- which arise from developments in scientific and technical knowledge and
- take account of the provisions of Article 9b (1), Article 9c (3), Article 9o and Article 9q (5)

shall be adopted in accordance with the procedure laid down in Article 23.

*Article 6*

1. A fee may be charged, according to the additive groups and the nature of the Community authorization requested, by the Member State acting as rapporteur for the examination of dossiers arising from the obligations laid down in Articles 4 (2), 9b (1), 9c (3) and 9g (4). This fee shall be paid at the time of submission of the dossier.

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2. Before 1 April 1999, the Council, acting by a qualified majority on a proposal from the Commission, shall adopt rules for the calculation of the level of the fee referred to in paragraph 1.

**▼M100***Article 7*

1. Member States and the Commission shall ensure that any information which, if disseminated, could affect industrial and commercial property rights is kept confidential.

2. Confidentiality shall not apply to:

- the name and composition of the additive,
- the physico-chemical and biological characteristics of the additive,
- the interpretation of the pharmacological, toxicological and ecotoxicological data relating to the additive,
- the analytical methods for monitoring the additive itself and the additive in premixtures, in the feedingstuffs and, where appropriate, in feed materials,
- the methods for testing for residues of the additive or metabolites thereof in animal products.

▼ **M100***Article 7a*

If an additive contains or consists of genetically modified organisms within the meaning of Article 2 (1) and (2) of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms<sup>(1)</sup>, a specific environmental risk assessment similar to that laid down in the abovementioned Directive shall be carried out; for this purpose, the following documents shall be included in the dossier submitted pursuant to Article 4 of this Directive in order to ensure compliance with the principles set out in Article 3a:

- a copy of any written consent or consents of the competent authorities to the deliberate release into the environment of genetically modified organisms for research and development purposes pursuant to Article 6 (4) of Directive 90/220/EEC and the result of the release(s) with respect to the risk in each case to human health and the environment,
- the complete technical dossier supplying the information requested in Annexes II and III to Directive 90/220/EEC and the environmental risk assessment resulting from this information; the results of any investigations performed for the purposes of research or development.

Articles 11 to 18 of Directive 90/220/EEC shall not apply to additives consisting of or containing genetically modified organisms.

*Article 8*

1. The Scientific Committee for Animal Nutrition established by Commission Decision 76/791/EEC<sup>(2)</sup> shall be responsible for assisting the Commission, at the latter's request, on all scientific questions relating to the use of additives in animal nutrition.

2. At the request of the Commission, the Member State acting as rapporteur shall ensure that all or part of the dossier referred to in Article 4 is officially forwarded to the members of the Committee referred to in paragraph 1.

ARRANGEMENTS APPLICABLE TO AUTHORIZATIONS FOR ADDITIVES LINKED TO THE PERSON RESPONSIBLE FOR PUTTING THEM INTO CIRCULATION

**Authorization given for 10 years***Article 9*

Additives as referred to in Article 2 (aaa) which meet the conditions laid down in Article 3a shall be authorized and included in Chapter I of the list referred to in Article 9t (b).

**Provisional authorization for a maximum of four years***Article 9a*

1. In the case of the additives referred to in Article 2 (aaa), provisional authorization may be given at Community level for the use of a new additive or a new use of an additive already authorized, provided that the conditions laid down in Article 3a (b), (c), (d) and (e) are met and it is reasonable to assume, in view of the available results, that the other condition laid down in Article 3a (a) is also met. These additives shall be included in Chapter II of the list referred to in Article 9t (b).

2. Provisional authorization as referred to in paragraph 1 may not exceed four years from the date on which it takes effect.

(1) OJ No L 117, 8. 5. 1990, p. 15. Directive as last amended by Directive 94/15/EC (OJ No L 103, 22. 4. 1994, p. 20).

(2) OJ No L 279, 9. 10. 1976, p. 35. Decision as amended by Decision 86/105/EEC (OJ No L 93, 8. 4. 1986, p. 14).

▼ **M100****Renewal of authorization after 10 years***Article 9b*

1. Community authorization of additives referred to in Article 2 (aaa) shall be valid for 10 years from the date on which final authorization takes effect and shall be renewable for 10-year periods. In the event of renewal, the authorization holder shall send to the Commission, via the Member State acting as rapporteur, an application accompanied by a dossier complying with the provisions to be laid down for the renewal of authorizations for additives in Directive 87/153/EEC. The application and the dossier shall be sent, at least one year before the date of expiry of the authorization, to the Commission, which shall acknowledge receipt thereof at the earliest opportunity. A copy of the renewal application, together with the dossier, shall be officially forwarded by the authorization holder via the Member State acting as rapporteur to the other Member States, which shall acknowledge receipt thereof at the earliest opportunity.
2. Articles 3, 3a, 4, 7, and 7a shall apply *mutatis mutandis* to applications for renewal.
3. Where, for reasons beyond the control of the authorization holder, no decision may be taken on the renewal application before the expiry date of the authorization, the period of authorization of the additive shall be automatically extended until the Commission takes a decision.

## DATA PROTECTION

*Article 9c*

1. In the case of the additives referred to in Article 2 (aaa), the scientific data and other information in the initial dossier submitted for the purpose of the first authorization may not be used for the benefit of other applicants for a period of 10 years:
  - (a) from the date on which the first authorization by means of regulation takes effect for the additives referred to in Article 9g (1), Article 9h (1) and Article 9i (1), or
  - (b) for other additives from the data on which the first authorization by means of regulation takes effect or counting from 1 October 1999 if the latter date of taking effect is earlier,

unless the applicant has agreed with the authorization holder that such data and information may be used.

During this period, however, authorizations for putting into circulation may be granted to persons other than the person responsible for first putting the additive into circulation provided that the conditions in Articles 3a and 4 are met.

2. Where additional information is supplied on an additive which has been provisionally authorized under Article 9a, for the purpose of obtaining authorization of the additive under Article 3a, that information shall be considered as an integral part of the initial dossier and shall consequently cease to be protected at the same time as the information in the initial dossier.
3. On expiry of the 10-year period referred to in paragraph 1, the findings of all or part of the evaluation conducted on the basis of the scientific data and information in the dossier which led to authorization of the additive may be used by the Commission or by a Member State for the benefit of another applicant for authorization to put an additive which has already been authorized into circulation.

In such a case, an application accompanied by a dossier in accordance with the provisions to be laid down for this purpose in Directive 87/153/EEC shall be addressed by the new applicant, via a Member State acting as rapporteur, to the Commission, which shall acknowledge receipt thereof as quickly as possible. A copy of the application, together with the dossier, shall be officially forwarded by the new applicant, via a Member State acting as rapporteur, to the other

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Member States, which shall acknowledge receipt thereof at the earliest opportunity.

The provisions of Articles 3, 3a, 4, 7 and 7a shall apply *mutatis mutandis*.

4. The provisions of paragraph 3 shall also apply to the use of data from a dossier concerning an additive which has been the subject of withdrawal of authorization at the request of the holder of that authorization.

5. The additional scientific data and information required for modification of the conditions for listing an additive or for renewal of the authorization in accordance with Article 9b (1) or any new scientific data or information provided during the period of authorization of the additive may not be used by the Commission or by a Member State for the benefit of another applicant for a period of five years from the date on which the authorization of a new use, the renewal or the submission of new scientific data or information takes effect.

Where the data-protection period granted for modification of the conditions for listing an additive expires before the end of the period provided for in paragraph 1, the five-year period shall be extended so that both periods expire simultaneously.

6. Without prejudice to paragraph 1, an applicant for an authorization for an additive referred to in Article 2 (3) (aaa) shall, before beginning toxicological tests on vertebrates, check whether his product or its active substance has not already been authorized. If necessary, he shall find out from a Member State's competent authorities whether the product or active substance concerned is the same as that already authorized.

If the product or active substance concerned has already been authorized, the applicant and the holder(s) of earlier authorizations shall take all necessary steps to reach agreement on sharing the use of information, in order not to repeat the toxicological tests on vertebrates.

If, however, the applicant and the holder(s) of previous authorizations for the same product do not reach agreement on sharing the information, the Member States may take national measures to oblige the applicant and the holder(s) of previous authorizations established within their territories to share the information, in order to avoid repeating toxicological tests on vertebrates undertaken on their territory and may lay down conditions for the use of the information while ensuring a reasonable balance between the interests of the parties concerned.

#### ARRANGEMENTS APPLICABLE TO AUTHORIZATION OF OTHER ADDITIVES

##### **Authorization without a time limit**

###### *Article 9d*

1. Additives as referred to in Article 2 (aaaa) which meet the conditions laid down in Article 3a shall be authorized and included in Chapter III of the list referred to in Article 9t (b).

2. Additives as referred to in Article 2 (aaaa) included in Annex I before 1 April 1998 shall be authorized and included in Chapter III of the list referred to in Article 9t (b).

##### **Provisional authorization for a maximum of four or five years**

###### *Article 9e*

1. In the case of the additives referred to in Article 2 (aaaa), provisional authorization may be given at Community level for the use of a new additive or a new use of an additive already authorized, provided that the conditions laid down in Article 3a (b), (c), (d) and (e) are met and it is reasonable to assume that the condition laid down in Article

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3a (a) is also met. These additives shall be included in Chapter IV of the list referred to in Article 9t (b).

2. Provisional authorization as referred to in paragraph 1 may not exceed four years from the date on which it takes effect.

3. Additives as referred to in Article 2 (aaa), included in Annex II before 1 April 1998, may continue to be the subject of national provisional authorizations; they shall be included in Chapter IV of the list referred to in Article 9t (b). The period of provisional authorization of these additives may not exceed five years taking account of the period of inclusion in Annex II referred to above.

TRANSITIONAL ARRANGEMENTS APPLICABLE TO AUTHORIZATIONS  
FOR ADDITIVES LINKED TO THE PERSON RESPONSIBLE FOR  
PUTTING THEM INTO CIRCULATION

*Article 9f*

Notwithstanding Article 3, Member States shall permit the additives listed in Annex B to be put into circulation.

**Additives included in Annex I before 1 January 1988**

*Article 9g*

1. Additives as referred to in Article 2 (aaaa) included in Annex I before 1 January 1988 shall be provisionally authorized as from 1 April 1998 and transferred to Chapter I of Annex B with a view to their re-evaluation as additives linked to a person responsible for putting them into circulation.

2. With a view to their re-evaluation, the additives as referred to in paragraph 1 must, before 1 October 1998, be the subject of new applications for authorization; such applications, accompanied by the monographs and the identification notes provided for in Articles 9n and 9o respectively, shall be addressed by the person responsible for the dossier on the basis of which the former authorization was granted or by his successor or successors, via the Member State acting as rapporteur, to the Commission, sending copies to the other Member States, which shall acknowledge receipt thereof.

3. In accordance with the procedure laid down in Article 23, provisional authorization of the additives shall be withdrawn through the adoption of a Regulation and they shall be deleted from the list in Chapter I of Annex B before 1 October 1999:

- (a) if the documents prescribed in paragraph 2 are not submitted within the time allowed or
- (b) if, after scrutiny of the documents, it is established that the monographs and identification notes are not in accordance with the date in the dossier on the basis of which the original authorization was given.

4. Member States shall ensure that the person responsible for putting an additive as referred to in paragraph 1 into circulation submits, as provided for in Article 4 and not later than 30 September 2000, the dossier referred to in Article 4 with a view to re-evaluation. Where he fails to do so, the authorization of the additive in question shall be withdrawn through the adoption of a regulation in accordance with the procedure laid down in Article 23 and it shall be deleted from the list in Chapter I of Annex B.

5. The Commission shall take all necessary measures to ensure that re-evaluation of the dossiers referred to in paragraph 4 is completed no later than three years after the dossier is submitted.

In accordance with the procedure laid down in Article 23, authorizations of the additives referred to in Article 1:

- (a) shall be withdrawn and they shall be deleted from the list in Chapter I of Annex B through the adoption of a regulation, or

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- (b) shall be replaced by authorizations linked to the person responsible for putting them into circulation for a period of 10 years through the adoption of a regulation taking effect no later than 1 October 2003 and included in Chapter I of the list referred to in Article 9t (b).
6. The provisions of Article 9b (3) shall apply *mutatis mutandis*.

**Additives included in Annex I after 31 December 1987***Article 9h*

1. Additives as referred to in Article 2 (aaa) included in Annex I after 31 December 1987 shall be authorized provisionally as from 1 April 1998 and transferred to Chapter II of Annex B with a view to their authorization for a period of 10 years as additives linked to a person responsible for putting them into circulation in accordance with paragraphs 2 and 3.
2. The additives referred to in paragraph 1 must, before 1 October 1998, be the subject of new applications for authorization; such applications, accompanied by the monographs and the identification notes provided for in Articles 9n and 9o respectively, shall be addressed by the person responsible for the dossier on the basis of which the former authorization was given or by his successor or successors, via the Member State acting as rapporteur, to the Commission, sending copies to the other Member States, which shall acknowledge receipt thereof.
3. In accordance with the procedure laid down in Article 23, provisional authorizations of the additives referred to in paragraph 1:
- (a) shall be withdrawn and they shall be deleted from the list in Chapter II of Annex B, through the adoption of a regulation, if the documents prescribed in paragraph 2 are not submitted within the time allowed or if, after scrutiny of the documents, it is established that the monographs or the identification notes are not in accordance with the data in the dossier on the basis of which the original authorization was given, or
- (b) shall be replaced by authorizations linked to the person responsible for putting them into circulation, which shall be given for a period of ten years through the adoption of a regulation taking effect no later than 1 October 1999 and included in Chapter I of the list referred to in Article 9t (b).
4. The provisions of Article 9b (3) shall apply *mutatis mutandis*.

**Additives included in Annex II before 1 April 1998***Article 9i*

1. Additives as referred to in Article 2 (aaa) included in Annex II before 1 April 1998 may continue to be the subject of national provisional authorizations; they shall be authorized and transferred to Chapter III of Annex B with a view to their authorization as additives linked to a person responsible for putting them into circulation; the period of provisional authorization of these additives may not exceed five years taking account of the period of inclusion in Annex II referred to above.
2. The additives as referred to in paragraph 1 must, before 1 October 1998, be the subject of new applications for authorization; such applications, accompanied by the monographs and identification notes provided for in Articles 9n and 9o respectively, shall be addressed by the person responsible for the dossier on the basis of which the former authorization was given or by his successor or successors, via the Member State acting as rapporteur, to the Commission, sending copies to the other Member States, which shall acknowledge receipt thereof.

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3. In accordance with the procedure laid down in Article 23, provisional authorizations of the additives referred to in paragraph 1:
- (a) shall be withdrawn and they shall be deleted from the list in Chapter III of Annex B through the adoption of a regulation if the documents prescribed in paragraph 2 are not submitted within the time allowed or if, after scrutiny of the documents, it is established that the monographs and identification notes are not in accordance with the data in the dossier on the basis of which the original authorization was given, or
  - (b) shall be replaced by provisional authorizations as referred to in paragraph 1 linked to the person responsible for putting them into circulation through the adoption of a regulation taking effect no later than 1 October 1999 and the additives shall be included in Chapter II of the list referred to in Article 9t (b).
4. The provisions provided for in Article 9b (3) shall apply *mutatis mutandis*.

*Article 9j*

Applications for authorization to put into circulation submitted between 1 April 1998 and 30 September 1999 in respect of which the Commission has not yet given a ruling at that date shall be examined in accordance with Articles 3, 3a, 7, 7a, 9, 9a, 9b, 9c, 9d, 9e, 9n and 9o, as appropriate.

## DISTRIBUTION AND USE OF ADDITIVES

*Article 9k*

1. Member States shall ensure that in the field of animal nutrition only additives authorized in accordance with this Directive may be put into circulation and that they may be used only if incorporated in feedingstuffs under the conditions set out in the authorization regulation.
2. Notwithstanding paragraph 1, additives belonging to groups other than 'antibiotics', 'coccidiostats and other medicinal substances', and growth promoters may be used if administered by a method other than incorporation in feedingstuffs, on condition that that method is provided for in the authorization regulation.
3. Member States shall, in particular, ensure that additives are added to feed materials and to straight feedingstuffs only where their use is expressly provided for in the authorization regulation.

## REGISTRATION

*Article 9l*

1. Where additives as referred to in Article 2 (aaa) are authorized, the person(s) responsible for putting them into circulation shall be given a registration number and the additive shall be given a Community registration number.
2. Authorized additives as referred to in Article 2 (aaaa) shall be given a Community registration number.

## WITHDRAWAL OF ADDITIVES

*Article 9m*

A regulation shall be adopted to withdraw the authorization of an additive:

- at the request of the person responsible for putting the additive into circulation, if the additive is one of those referred to in Article 2 (aaa),
- if any of the conditions for the authorization of the additive referred to in Article 3a are no longer met,

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- if a standard sample of the additive is not supplied to the official authorities which have requested it or if an additive put into circulation does not correspond to the standard sample of the authorized additive,
- if a reference sample of the active substance is not supplied to the official authorities which have requested it,
- if the person responsible for putting the additive into circulation does not provide, within a given period of time, the information requested by a person responsible at the Commission.

However, such additives may continue to be authorized in order to use up stocks for a period of no longer than one year if at least the conditions laid down in Article 3a (b) and (e) continue to be met.

## MONOGRAPHS AND IDENTIFICATION NOTES

*Article 9n*

1. In accordance with Directive 87/153/EEC, Member States shall ensure that applicants present a monograph for additives as referred to in Article 2 (aaa).

2. During the authorization procedure for additives as referred to in Article 2 (aaa), the Standing Committee for Feedingstuffs shall give an opinion, if appropriate after having made the necessary amendments, on the monograph of the additive presented in the dossier provided for in Article 4.

The Commission shall approve the opinion given by the Standing Committee for Feedingstuffs on the monograph and its amendments in accordance with the procedure laid down in Article 23.

3. Monographs may also be approved for additives other than those referred to in paragraph 1 in accordance with the procedure laid down in paragraph 2.

4. The competent authorities of the Member States shall have recourse to the monograph:

- (a) to determine whether an additive for which authorization to put into circulation has been requested constitutes an innovation or should be considered as a copy;
- (b) to ascertain whether the additive put into circulation actually corresponds to the additive described in the dossier on the basis of which the Community authorization was granted.

5. Subsequent amendments to be made to monographs on account of developments in scientific and technical knowledge shall be submitted to the Standing Committee for Feedingstuffs for its opinion in accordance with the procedure laid down in Article 23.

*Article 9o*

1. In accordance with Directive 87/153/EEC, Member States shall ensure that the applicant presents an identification note summarizing the characteristics and properties of the additive. In the case of the additives referred to in Article 2 (aaa), or should Article 9n (3) be applied, the identification note shall contain a summary of the most important characteristics and properties given in the monograph referred to in Article 9n.

2. The following shall be adopted in accordance with the procedure laid down in Article 23:

- the identification note,
- subsequent amendments to the identification note as a result of developments in scientific and technical knowledge.

3. In order to facilitate identification of the additives referred to in paragraph 1 during official checks, the identification note provided for in that paragraph shall be published in the *Official Journal of the European Communities*.



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## STANDARD SAMPLE

*Article 9p*

1. For the additives referred to in Article 2 (aaa) a standard sample having the characteristics and properties described in the monograph referred to in Article 9n together with a reference sample of the active substance shall be made available, upon request, to the national inspection authorities of the Member States by the person responsible for putting them into circulation.
2. If the characteristics or properties of the additive are modified, a new standard sample corresponding to the new monograph shall be provided.
3. Detailed rules concerning the provision and maintenance of standard samples shall be adopted in accordance with the procedure laid down in Article 23.

## MIXTURES AND ADDITIVE LEVELS

*Article 9q*

1. The maximum and minimum levels set for certain additives shall refer to complete feedingstuffs with a moisture content of 12 % insofar as no special provisions are laid down in the authorization regulation.

If the substance permitted as an additive also exists in the natural state in certain feed materials, the amount of additive to be incorporated shall be calculated so that the total of the elements added and the elements present naturally does not exceed the maximum level provided for in the authorization regulation.

2. The mixing of additives shall be permitted in premixtures and feedingstuffs only where there is physico-chemical and biological compatibility between the components of the mixture in relation to the effects desired.
3. Unless the mixture concerned is the subject of a specific authorization as an additive, Member States shall require that:
  - (a) antibiotics and growth promoters may not be mixed together, either with substances from their own group or with substances from the other group;
  - (b) coccidiostats and other medicinal substances may not be mixed with antibiotics and growth promoters where coccidiostats also act, for the same category of animal, as an antibiotic or as a growth promoter;
  - (c) coccidiostats and other medicinal substances may not be mixed together if their effects are similar.
4. Mixing antibiotics, growth promoters, coccidiostats and other medicinal substances with micro-organisms shall be prohibited unless such a mixture is authorized by the regulation authorizing the micro-organisms.
5. By way of derogation from Article 3 and paragraphs 2 and 3 of this Article, Member States may authorize, but only for practical tests conducted for scientific purposes and for non-commercial ends, the use as additives of products which are not authorized at Community level or the use of additives under conditions other than those laid down in the authorization regulation, provided that:
  - the tests are carried out in accordance with the principles and conditions to be laid down in Directive 87/153/EEC, and
  - an adequate official inspection has been performed.

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## AMENDMENTS TO THE ANNEXES

*Article 9r*

Amendments to be made to the Annexes shall be adopted in accordance with the procedure laid down in Article 23.

## INFORMATION ON PRODUCERS OF ADDITIVES

*Article 9s*

Member State shall ensure that the persons responsible for putting the additives referred to in Article 2 (aaa) into circulation forward to the Commission as quickly as possible the name or corporate name and the address or registered office of the producers to whom they have granted the right to manufacture the additive and, if the producers are established in a third country, also the name or corporate name and the address or registered office of their representatives in the Community.

## PUBLICATION IN THE OFFICIAL JOURNAL

*Article 9t*

The Commission shall publish in the *Official Journal of the European Communities*, 'C' Series, not later than 30 November each year:

- (a) the list of persons responsible for putting additives into circulation as referred to in Article 9s, the names of the producers to whom they have granted the right to manufacture the additives and their representatives in the Community if such producers are established in a third country;
- (b) the list of authorized additives subdivided as follows:
  - Chapter I: list of additives linked to a person responsible for putting them into circulation and authorized for a period of 10 years,
  - Chapter II: list of additives linked to a person responsible for putting them into circulation and authorized on a provisional basis for no longer than four years or five years in the case of additives which have been the subject of provisional authorization before 1 April 1998,
  - Chapter III: list of other additives authorized for an unlimited period,
  - Chapter IV: list of other additives authorized on a provisional basis for no longer than four years or five years in the case of additives which have been the subject of provisional authorization before 1 April 1998.

## PACKAGING

▼ **M51***Article 10*

Member States shall require that additives and premixtures may be marketed only in closed packages or closed containers. Member States shall require that packages or containers must be closed in such a way that the fastener is damaged on opening and cannot be re-used.

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## SAFEGUARD AND MEASURES

▼ **M51***Article 11*

1. Where a Member State, as a result of new information or of a reassessment of existing information made since the provisions in question were adopted, has detailed grounds for establishing that the use of one of the additives ► **M100** authorized ◀ or its use in conditions which may be specified constitutes a danger to animal or human health or the environment although it complies with the provisions of this

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Directive, that Member State may temporarily suspend or restrict application of the provisions in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving reasons for its decision.

2. The Commission shall, as soon as possible, examine the grounds cited by the Member State concerned and consult the Member States within the Standing Committee for Feedingstuffs; it shall then deliver its opinion without delay and take the appropriate measures.

3. Should the Commission consider that amendments to the Directive are necessary in order to mitigate the difficulties mentioned in paragraph 1 and to ensure the protection of human or animal health or the environment, it shall initiate the procedure laid down in Article 24 with a view to adopting these amendments; the Member State which has adopted safeguard measures may in that event retain them until the amendments enter into force.

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## ADDITIVE LEVELS IN COMPLEMENTARY FEEDINGSTUFFS

**▼ M51***Article 12*

1. Member States shall require that supplementary feedingstuffs, diluted as specified, may not contain levels of the additives named in this Directive which exceed those fixed for complete feedingstuffs.

2. Member States may require that the levels of antibiotics, coccidiostats and other medicinal substances, growth promoters, D vitamins and antioxidants in supplementary feedingstuffs may exceed the maximum levels fixed for complete feedingstuffs in the case of:

- (a) supplementary feedingstuffs which a Member State has authorized to be made available to all users, provided that their level of antibiotics, D vitamins or growth promoters does not exceed five times the fixed maximum level;
- (b) supplementary feedingstuffs which are intended for certain species of animal and which a Member State is permitted to authorize to be made available within its territory to all users because of special feeding systems, provided that their level does not exceed:
  - for antibiotics and growth promoters, 1 000 mg/kg and, provided that the use of these substances is permitted, 2 000 mg/kg in the case of cattle for fattening;
  - for antioxidants, coccidiostats and other medicinal substances, five times the fixed maximum level;
  - for D vitamins, 200 000 IU/kg.

Member States shall prescribe that if, in the manufacture of supplementary feedingstuffs, recourse is had to the possibility referred to in (a), the possibility referred to in (b) may not be made use of at the same time.

3. Where paragraph 2 is invoked, Member States shall require that the feedingstuff has one or more compositional characteristics (as regards, for example, proteins or minerals) which in practice ensure that the level of additives fixed for complete feedingstuffs is not exceeded and that the feedingstuff is not used for other species of animal.

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## RULES FOR THE DISTRIBUTION AND INCORPORATION IN FEEDINGSTUFFS OF ADDITIVES AND PREMIXTURES

*Article 13*

1. Member States shall require that certain additives covered by this Directive, premixtures prepared from those additives with a view to their being incorporated in compound feedingstuffs and compound feedingstuffs containing those premixtures may be put into circulation

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or used only by the establishments or intermediaries which meet the conditions laid down, as appropriate, in Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector<sup>(1)</sup>.

2. Member States shall require that:

- (a) additives referred to in Part A of Annex A may be supplied only by approved establishments:
  - (i) to intermediaries or establishments which manufacture premixtures and which have been approved in accordance with the provisions laid down in Article 3 (1) or Article 2 (2) (b) respectively of Directive 95/69/EC, and
  - (ii) in the form of premixtures, only to intermediaries or establishments which manufacture compound feedingstuffs with a view to putting them into circulation or for the exclusive requirements of their holding and which have been approved in accordance with the provisions laid down in Article 3 (1) or Article 2 (2) (c) or (e) respectively of the above Directive;
- (b) additives listed in Part B of Annex A may be supplied only by approved establishments:
  - (i) to intermediaries or establishments which manufacture premixtures and which have been approved in accordance with the provisions laid down in Article 3 (1) or Article 2 (2) (b) respectively of the above Directive, and
  - (ii) in the form of premixtures, only to:
    - intermediaries which have been approved in accordance with the provisions laid down in Article 3 of the above Directive, or
    - establishments which manufacture compound feedingstuffs with a view to putting them into circulation or for the exclusive requirements of their holding and which have been registered in accordance with the provisions laid down in Article 7 (2) (c) or (d) respectively of the said Directive or, as appropriate, approved in accordance with the provisions laid down in Article 2 (2) (c) or (e) of this Directive.

3. Member States shall require that additives referred to in Annex A (a) and (B) may be incorporated in compound feedingstuffs only if they have been prepared beforehand in the form of premixtures containing a carrier substance by establishments which meet the conditions laid down in Article 2 (2) (b) of Directive 95/69/EC. Such premixtures may be incorporated in compound feedingstuffs only in a proportion of at least 0,2 % by weight.

By way of derogation from the first subparagraph, Member States may allow premixtures to be incorporated in compound feedingstuffs in a proportion as low as 0,05 % by weight, provided that the quantitative and qualitative composition of the premixture so permits and that they have first established that the establishments satisfy the conditions set out in Chapter I.2 (b) of the Annex, with a view to achieving homogeneous distribution of premixtures and observing the additive levels set for the whole feedingstuff.

These manufacturers as referred to in the second paragraph shall be entered on the national list under a special heading as follows: 'Manufacturers of compound feedingstuffs authorized to use a minimum proportion of 0,05 % by weight of premixtures'.

4. By way of derogation from paragraph 2, Member States shall require that:

- (a) additives referred to in Annex A (B) may be supplied to approved intermediaries or registered establishments which manufacture

<sup>(1)</sup> OJ No L 332, 30. 12. 1995, p. 15.

**▼M100**

compound feedingstuffs for pets and fulfil ►C9 the conditions laid down, as appropriate, in Article 3(1) or Article 7(2)(c) or (d) of Directive 95/65/EC; ◀

- (b) additives referred to in Annex A (A) or (B) may be delivered at the last stage of circulation to establishments which manufacture compound feedingstuffs, provided that:
- the Community regulation authorizing the additive provides, in the case of a specific preparation of the additive, for direct addition to feedingstuffs, and
  - the manufacturer of compound feedingstuffs is approved in accordance with Article 2 (2) (c) of the above Directive for the additives referred to in Annex A (A) or is registered in accordance with Article 7 (2) (c) of the above Directive for the additives referred to in Annex A (B), and
  - it has been checked on the spot that the manufacturer is in possession of the appropriate technology defined in Chapter I (3) (b) or Chapter II (c) of the Annex to the above Directive in order to add the preparation in question directly to the compound feedingstuff.

Such manufacturers shall appear on the national list under a special heading as follows: ‘Manufacturers of compound feedingstuffs referred to in point (b) authorized to add antibiotics, coccidiostats and other medicinal substances, and growth promoters directly to compound feedingstuffs’ or ‘Manufacturers of compound feedingstuffs authorized to add copper, selenium and vitamins A and D directly to compound feedingstuffs’.

5. By way of derogation from Article 7 of Directive 95/69/EC and paragraphs 1 and 2 of this Article, Finland and, as regards that part of its territory situated to the north of latitude 60°, Sweden shall be authorized, in view of the special feeding conditions on their farms, to allow premixtures of vitamins, provitamins and chemically well-defined substances having similar effect to be supplied to stock farmers for direct addition to feed materials of vegetable origin, provided that:
- the directions for use state precisely the dosage to be complied with according to the species or category of animals and the type of fodder used, and
  - special measures are taken by Finland and Sweden to monitor use of such premixtures.

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6. Paragraphs 1 to 3 shall apply without prejudice to Article 4(2) and Article 9(2) of Directive 95/69/EC.

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## LABELLING OF ADDITIVES

*Article 14*

1. Member States shall require that authorized additives may be put into circulation for use in feedingstuffs only if the following particulars, which must be clearly visible, readily legible and indelible and must place responsibility on the producer, packer, importer, seller or distributor established within the Community, are given on the package, the container or a label affixed thereto:
- A. for all additives, with the exception of enzymes and micro-organisms:
- (a) the specific name given to the additive upon authorization, the EC registration number of the additive and, in the case of an additive within the meaning of Article 2 (aaa), the trade name and the registration number given to the person responsible for putting it into circulation;
  - (b) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this paragraph;

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- (c) the net weight and, in the case of liquid additives, either the net volume or the net weight;
  - (d) as applicable, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of Directive 95/69/EC or the registration number assigned to the establishment or the intermediary pursuant to Article 10 of the above Directive.
- B. In addition, with regard to:
- (a) antibiotics, growth promoters, coccidiostats and other medicinal substances: the name or business name and the address or registered place of business of the manufacturer, if he is not responsible for the particulars in the label, the active-substance level, the expiry date of the guarantee or the storage life from the date of manufacture, the batch reference number and the date of manufacture, the directions for use and, where appropriate, a safety recommendation regarding use in the case of additives which are the subject of special provisions upon authorization;
  - (b) vitamin E: the alpha-tocopherol level and the expiry date of the guarantee of that level or storage life from the date of manufacture;
  - (c) vitamins, other than vitamin E, provitamins and substances having a similar effect: the active-substance level and the expiry date of the guarantee of that level or storage life from the date of manufacture;
  - (d) trace elements, colourants including pigments, preserving agents and other additives, with the exception of those belonging to the enzyme and micro-organism groups: the active-substance level.
- C. For additives belonging to the groups:
- (a) of enzymes: the specific name of the active component or components in accordance with their enzyme activities, in conformity with the authorization given, the International Union of Biochemistry identification number, units of activity <sup>(1)</sup> (units of activity per gram or units of activity per millilitre), the EC registration number of the additive, the name or business name and the address or registered place of business of the person responsible for the particulars on the label, the name or business name and the address or registered place of business of the manufacturer, if he is not responsible for the particulars on the label, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of Directive 95/69/EC, the expiry date of the guarantee or the storage life from the date of manufacture, the batch reference number and the date of manufacture, the directions for use specifying in particular the recommended dose, in the form of a range if appropriate, in accordance with the percentage(s) by weight of target feed material(s) per kilogram of the whole feedingstuff in accordance with the requirements laid down on a case-by-case basis in the authorization for the additive and, where applicable, safety recommendations as provided for in the authorization for the additive, the net weight and, in the case of liquid additives, either the net volume or the net weight, where appropriate indication of special significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization for the additive;
  - (b) of micro-organisms: identification of the strain(s) in accordance with the authorization granted, the file number of the strain(s), the number of colony-forming units (CFU per gram), the EC registration number of the additive, the name or business name and the address or registered place of business of the person responsible for the particulars on the label, the name or business

<sup>(1)</sup> Units of activity expressed in micromoles of product released per minute, per gram of enzyme preparation.

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name and the address or registered place of business of the manufacturer, if he is not responsible for the particulars on the label, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of Directive 95/69/EC, the expiry date of the guarantee or the storage life from the date of manufacture, the batch reference number and the date of manufacture, the directions for use and, where applicable, safety recommendations as provided for in the authorization for the additive, the net weight and, in the case of liquid additives, either the net volume or the net weight, where appropriate an indication of special significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive.

2. Member States shall require that the specific name of the additive may be accompanied, in cases where the indications are not required by virtue of paragraph 1:

- (a) by the trade name;
- (b) by the name or business name and the address or registered place of business of the manufacturer, if he is not responsible for the particulars on the label, the directions for use and, where appropriate, a safety recommendation regarding use.

3. Member States shall require that information other than that required or authorized pursuant to paragraphs 1 and 2 may appear on packages, containers or labels, provided that they are clearly separated from the abovementioned marking particulars.

*Article 15*

1. Member States shall require that premixtures may be marketed only if the following particulars, which must be clearly visible, readily legible and indelible and must place responsibility on the producer, packer, importer, seller or distributor established within the Community, are given on the package, the container or a label affixed thereto:

A. For all premixtures:

- (a) the description 'premixture';
- (b) directions for use, and any safety recommendations regarding the use of the premixtures;
- (c) the animal species or category of animals for which the premixture is intended;
- (d) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this paragraph;
- (e) the net weight and, in the case of liquids, either the volume or net weight;
- (f) as applicable, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of Directive 95/69/EC or the registration number assigned to the establishment or the intermediary pursuant to Article 10 of the above Directive.

B. In addition, for the premixtures incorporating the additives listed below:

- (a) antibiotics, growth promoters, coccidiostats and other medicinal substances: the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the details on the label, specific name given to the additive upon authorization, active substance level and expiry date of the guarantee of that level, or storage life from the date of manufacture;
- (b) substances having antioxidant effects: specific name given to the additive upon authorization, and active substance level, provided that a maximum level is fixed for complete feeding-stuffs on authorization of the additive;

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- (c) colourants, including pigments: specific name given to the additive upon authorization, and active substance level, provided that a maximum level is fixed for complete feedingstuffs upon authorization of the additive;
  - (d) vitamin E: specific name given to the additive upon authorization, alpha-tocopherol level and expiry date of the guarantee of that level or storage life from the date of manufacture;
  - (e) vitamins other than vitamin E, provitamins and substances having a similar effect: specific name given to the additive upon authorization, active substance level and expiry date of the guarantee of that level or storage life from the date of manufacture;
  - (f) trace elements: specific name given to the additive upon authorization, and level of the various elements insofar as a maximum level is fixed for complete feedingstuffs upon authorization of the additive;
  - (g) preserving agents: specific name given to the additive upon authorization, and active substance level, provided that a maximum level is fixed for complete feedingstuffs upon authorization of the additive;
  - (h) enzymes: the specific name of the active component(s) according to its (their) enzymatic activity(ies) in accordance with the authorization given, the identification number according to the International Union of Biochemistry, the activity units (activity units per g or activity units per ml), the additive's EC registration number, the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label, the expiry date of the guarantee or the storage life from the date of manufacture, the batch reference number and the date of manufacture, the directions for use specifying in particular the recommended dose, in the form of a range if appropriate, in accordance with the percentage(s) by weight of target feed material(s) per kilogram of the whole feedingstuff in accordance with the requirements laid down on a case-by-case basis in the authorization for the additive and, where applicable, indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive;
  - (i) micro-organisms: the identification of the strain(s) in accordance with the authorization given, the file number of the strain(s) in accordance with the authorization given, the file number of the strain(s), the number of colony-forming units (CFU/g), the additive's EC registration number, the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label, the expiry date of the guarantee of the storage life from the date of manufacture and, where applicable, indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive;
  - (j) other additives belonging to the groups referred to in (b) or (i) for which no maximum level is laid down and additives belonging to other groups authorized: specific name given to the additive upon authorization and active substance level, provided that these additives fulfil a function in the feedingstuff as such and the amounts present can be determined by official methods of analysis or, failing this, by valid scientific methods.
2. Member States shall require that:
- (a) the specific name of additives may be accompanied by the trade-name;
  - (b) the name of the producer of the additives referred to in paragraph 1 (B) (a) may be indicated in the labelling of premixtures. However, they may stipulate that this indication shall be compulsory;



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- (c) the specific name of the additives authorized may be accompanied by the additive's EC registration number.
3. Where, pursuant to paragraph 1, the expiry date of the guarantee or storage life from the date of manufacture of several additives belonging to the same group or different groups has to be stated, Member States shall require that a single date of guarantee or a single reference to the storage life may be indicated for all the additives, namely the deadline which will be reached first.
4. Member States shall require that information other than that required or authorized pursuant to paragraphs 1 to 3 may appear on packages, containers or labels, provided that they are clearly separated from the abovementioned marking particulars.

*Article 16*

1. Member States shall require that feedingstuffs incorporating the additives belonging to the groups listed below may be put into circulation only if the following particulars, which must be clearly visible, readily legible and indelible and must place responsibility on the producer, packer, importer, seller or distributor established within the Community, are given on the package, the container or a label affixed thereto:
- (a) for antibiotics, coccidiostats and other medicinal substances and growth promoters: the specific name given to the additive upon authorization, the active substance level and the expiry date of the guarantee of that level or storage life from the date of manufacture, the approval number assigned to the establishment in accordance with Article 5 of Directive 95/69/EC;
- (b) for substances having antioxidant effects:
- in the case of pet foods: use of the words 'with antioxidant' followed by the specific name given to the additive upon authorization,
  - in the case of compound feedingstuffs other than pet foods: the specific name given to the additive upon authorization;
- (c) for colourants, including pigments provided that these are used for the colouration of feedingstuffs or animal products:
- in the case of pet foods: use of the words 'colourant' or 'coloured with' followed by the specific name given to the additive upon authorization,
  - in the case of compound feedingstuffs other than pet foods: the specific name given to the additive upon authorization;
- (d) for vitamin E: the specific name given to the additive upon authorization, the alpha-tocopherol level and the expiry date of the guarantee of that level or storage life from the date of manufacture;
- (e) for vitamins A and D: the specific name given to the additive upon authorization, the active substance level and the expiry date of the guarantee of that level or storage life from the date of manufacture;
- (f) for copper: the specific name given to the additive upon authorization and the level expressed in Cu;
- (g) for preserving agents:
- in the case of pet foods: use of the words 'preservative' or 'preserved with' followed by the specific name given to the additive upon authorization,
  - in the case of compound feedingstuffs other than pet foods: the specific name given to the additive upon authorization;
- (h) for enzymes: the specific name of the active constituent(s) according to its (their) enzymatic activity(ies) in accordance with the authorization given, the identification number according to the International Union of Biochemistry, the activity units (activity units per kilogram or activity unit per litre), the EC registration number of the additive, the expiry date of the guarantee or the storage life from the date of manufacture and, where applicable, indication of any particular significant characteristic due to the

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manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive;

- (i) for micro-organisms: the identification of the strain(s) in accordance with the authorization given, the file number of the strain(s), the number of colony-forming units (CFU/kg), the EC registration number of the additive, the expiry date of the guarantee or the storage life from the date of manufacture and, where applicable, indication of any particular significant characteristic due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive.

2. In addition to the particulars provided for by paragraph 1, particulars concerning the proper use of the feedingstuffs may be laid down in the authorization of the additive in accordance with the procedure provided for in Article 23.

Member States shall require that these particulars must appear on the package or the container or on a label affixed thereto.

3. The presence of trace elements other than copper and of vitamins other than vitamins A, D and E, provitamins and additives having a similar effect may be indicated if the amounts of these substances can be determined by official methods of analysis or, failing this, by valid scientific methods of analysis. In such cases the following details shall be given:

- (a) for trace elements other than copper: the specific name of the additive in accordance with the authorization given and level of the various elements;
- (b) for vitamins other than vitamins A, D and E, provitamins and substances having a similar chemical effect: the specific name of the additive in accordance with the authorization given, the active substance level and the expiry date of the guarantee of that level or storage life from the date of manufacture;

4. Member States shall require that:

- (a) the details provided for in paragraphs 1 to 3 shall be printed close to the particulars which have to appear on the package, container or the label affixed thereto in accordance with Community rules on feedingstuffs;
- (b) where a level or a quantity is stated pursuant to paragraphs 1 to 3, such statement shall refer to the amount of additive incorporated in the feedingstuff;
- (c) the details of additives may be accompanied by the EC registration number of the additive or the trade name where those particulars are not required by virtue of paragraph 1.

5. Where, pursuant to paragraph 1, the expiry date of the guarantee or storage life from the date of manufacture of several additives belonging to the same group or different groups has to be stated, Member States shall require that a single date of guarantee or a single reference to the storage life from the date of manufacture may be indicated for all the additives, namely the deadline which will be reached first.

6. In the case of feedingstuffs distributed by road tankers or similar vehicles or in bulk, the details provided for in paragraphs 1 to 3 shall be given in the accompanying document.

Where small quantities intended for the end-user are involved, it shall be sufficient for such details to be conveyed to the purchaser by a suitable notice.

7. Member States shall require that, in the case of pet foods containing colourants, preservatives or substances having antioxidant effects and put up in packages having a net weight of not more than 10 kilograms, it shall be sufficient for the package to bear the words

**▼ M100**

‘coloured with’, or ‘preserved with’, or the words ‘with antioxidant’ as appropriate, followed by the words ‘EC additives’, provided that:

- (a) the package, container or label bears a reference number by means of which the feedingstuff may be identified, and
- (b) the manufacturer gives, on request, the specific name, or names, of the additive or additives used.

8. Any reference to additives other than in the form provided for in this Directive shall be prohibited.

**▼ M109***Article 16a*

Articles 14 to 16 referring to the approval and registration numbers provided for in Directive 95/69/EC shall apply from 1 April 2001.

**▼ M51***Article 17*

1. Without prejudice to the provisions of Directive 79/373/EEC<sup>(1)</sup>, Member States shall require that supplementary feedingstuffs which contain additives in excess of the maximum levels fixed for complete feedingstuffs may be placed on the market only if the directions for use state, according to the species and age of the animal, the maximum quantity in grams or kilograms of supplementary feedingstuff to be given per animal per day.

**▼ M100**

This information must be in accordance with the conditions of use prescribed upon authorization of the additive.

**▼ M51**

This provision shall not apply to products delivered to manufacturers of compound feedingstuffs or to their suppliers.

2. The declaration referred to in paragraph 1 shall be so formulated that, when it is correctly followed, the proportion of additives does not exceed the maximum level fixed for complete feedingstuffs.

*Article 18*

Where feedingstuffs are marketed in other Member States the details referred to in Articles 14 to 17 shall be given in at least one of the official languages of the country of destination.

*Article 19*

Member States shall ensure that additives, premixtures and feedingstuffs which conform to this Directive are subject only to the marketing restrictions provided for in this Directive.

*Article 20*

Member States shall ensure that livestock products are not subject to any marketing restriction as a result of the application of this Directive.

**▼ M100**

## INSPECTION MEASURES

**▼ M51***Article 21*

1. Member States shall in particular take all necessary measures to ensure that additives, premixtures and feedingstuffs put on the market are officially checked, at least by random sampling, in respect of the identity of the additives used and to verify that the other conditions laid down in this Directive are satisfied.

<sup>(1)</sup> OJ No L 86, 6. 4. 1979, p. 30.

**▼ M51**

To this end, they shall require in particular that undertakings which intend to manufacture additives or to put them on the market must first inform the competent authorities thereof.

2. Under the procedure provided for in Article 23, margins of tolerance may be fixed, to be allowed where there is a discrepancy between the result of the official check and the stated content of the additive in the compound feedingstuff.

**▼ M100**

## MONITORING OF UNDESIRABLE INTERACTIONS

*Article 21a*

Where there is found to be unforeseen undesirable interaction between additives referred to in Article 2 (aaa) and other additives or veterinary medicines, Member States shall require that the person responsible for putting the additive into circulation, or his representative within the Community where additives originate in third countries, gathers all the relevant information and forwards it to the competent authorities.

## EXPORTS TO THIRD COUNTRIES

**▼ M51***Article 22*

This Directive shall not apply to additives, premixtures and feeding-stuffs which are shown, at least by an appropriate indication, to be for export to third countries.

**▼ M100**

## IMPLEMENTATION POWERS OF THE COMMISSION

**▼ M51***Article 23*

1. Where the procedure laid down in this Article is to be followed, matters shall be referred without delay by (SIC! by) the chairman, either on his own initiative or at the request of a Member State, to the Standing Committee for Feedingstuffs, hereinafter called 'the Committee'.

**▼ A3**

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

**▼ M51**

► A3 3. ◀ The Commission shall adopt the measures and implement them forthwith where they are in accordance with the opinion of the Committee. Where they are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall adopt the measures by a qualified majority.

If the Council has not adopted any measures within three months of the proposal being submitted to it, the Commission shall adopt the proposed measures and implement them forthwith, except where the Council has voted by a simple majority against such measures.

*Article 24*

1. Where the procedure laid down in this Article is to be followed, matters shall be referred to the Committee without delay by the

▼ **M51**

chairman, either on his own initiative or at the request of a Member State.

▼ **A3**

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion within two days. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

▼ **M51**

► **A3** 3. ◀ The Commission shall adopt the measures and implement them forthwith where they are in accordance with the opinion of the Committee. Where they are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall adopt the measures by a qualified majority.

If the Council has not adopted any measures within 15 days of the proposal being submitted to it, the Commission shall adopt the proposed measures and implement them forthwith, except where the Council has voted by a simple majority against such measures.

▼ **M100**

## FINAL PROVISIONS

▼ **M51***Article 25*

A decision on the transfer of antibiotics, coccidiostats and other medicinal substances, together with preparations based on these products, to Directive 81/851/EEC and to future rules on medicinal feedingstuffs shall be adopted by the Council acting unanimously on a proposal from the Commission once the degree of harmonization with regard to the free movement of products in the sector of veterinary medicinal products and medicated feedingstuffs has reached a level comparable to that obtaining with regard to additives.

*Article 26*▼ **B**

Member States shall, within two years following notification thereof, bring into force the laws, regulations, or administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

▼ **M77**

However, in the case of the territory of the former German Democratic Republic, the Federal Republic of Germany may:

- maintain the provisions applicable prior to unification under which the use of the following additives in feedingstuffs is authorized:
  - Olaquinox,
  - Nourseothricine,
  - Ergambur.

This derogation shall expire on the date of the Decision to be taken, in accordance with Article 7, on the authorization or prohibition of the use of the additives listed above, and by 31 December 1992 at the latest. The Federal Republic of Germany shall ensure that those additives and any feedingstuffs into which they are incorporated are not dispatched to other parts of the Community;

- derogate, until 31 December 1991, from the labelling provisions in Articles 14, 15 and 16 for the additives, additive pre-mixtures and compound feedingstuffs to which additives have been added, produced in the territory in question.

▼ M51

*Article 27*

▼ B

This Directive is addressed to the Member States.

▼ **M100**

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*Annex A*

referred to in Article 13

PART A

- Antibiotics: all additives belonging to this group
- Coccidiostats and other medicinal substances: all additives belonging to this group
- Growth promoters: all additives belonging to this group

PART B

- Trace elements: copper and selenium
- Vitamins, provitamins and chemically well-defined substances with similar effects: vitamins A and D.

## ANNEX B

## CHAPTER I

**Additives linked to a person responsible for putting them into circulation, inserted in Annex I before 1 January 1988**

Registra- tion number	Name and registration number of person responsible for marketing (*)	Additive	Chemical name, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provi- sions
						mg/kg complete feeding- stuff			
		A. Antibiotics							
		B. Coccidiostats and other medicinal substances							
		C. Growth promoters							

(\*) Authorization to be linked to the person responsible with effect from 1 October 1999.

## CHAPTER II

**Additives linked to a person responsible for putting them into circulation, inserted in Annex I after 31 December 1987**

Registra- tion number	Name and registration number of person responsible for marketing (*)	Additive	Chemical name, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provi- sions
						mg/kg complete feeding- stuff			
		A. Antibiotics							
		B. Coccidiostats and other medicinal substances							



▼ **M100**

Registration number	Name and registration number of person responsible for marketing (*)	Additive	Chemical name, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions
						mg/kg complete feeding-stuff			
		C. Growth promoters							

(\*) Authorization to be linked to the person responsible with effect from 1 October 1999.

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## CHAPTER III

▼ **M105**

## Additives linked to a person responsible for marketing, inserted in Annex II before 1 April 1998

## A. Antibiotics

Regis- tration number	Name and registration number of person responsible for marketing (¹)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minim- um content		Maximum content	Other provisions	Duration of authorisation
						mg/kg complete feedingsstuff	mg/kg complete feedingsstuff			
31		Bacitracin zinc	$C_{66}H_{103}O_{16}N_{17}SZn$ (polypeptide containing 12 to 20 % zinc)	Chickens for fattening	—	5	50	—	17. 7. 1999 (²)	
33		Avilamycin	$C_{57,62}H_{82,90}Cl_{1,2}O_{31,32}$ (mixture of oligosaccharides of the orthosomycin group produced by <i>Streptomyces viri- dochromogenes</i> , NRRL 2860) Factor composition: — Avilamycin A: not less than 60 % — Avilamycin B: not more than 18 % — Avilamycins A + B: not less than 70 % — Other single avilamycins: not more than 6 %	Pigs  Turkeys	6 months	5	50	—	17. 7. 1999 (²)	
					—	5	10	—	30. 9. 1999 (³)	

## ▼ M105

## B. Coocciostats and other medicinal substances

Regis- tration number	Name and registration number of person responsible for marketing (¹)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions	Duration of authorisation
						mg/kg complete feedingstuff	mg/kg complete feedingstuff			
26		Salinomycin sodium	$C_{42}H_{69}O_{11}Na$ (sodium salt of a polyether monocarboxylic acid produced by <i>Streptomyces albus</i> ) Elaiophyllin content: less than 42 mg per kg of salinomycin sodium 17-epi-20-desoxysalinomycin content: less than 40 g per kg of salinomycin sodium	Rabbits for fattening	—	20	25	Use prohibited at least five days before slaughter. Indicate in the instructions for use: — 'Dangerous for equines' — 'This feedingstuff contains an ionophore; simultaneous use with certain medicinal substances (e.g. tiamulin) can be contra indicated'	30. 9. 1999 (⁴)	
				Chickens reared for laying	12 weeks	30	50	Indicate in the instructions for use: — 'Dangerous for equines' — 'This feedingstuff contains an ionophore; simultaneous use with certain medicinal substances (e.g. tiamulin) can be contra indicated'	30. 9. 1999 (⁵)	
27		Diclazuril	(±)-4-chlorophenyl(2,6-dichloro-4- (2,3,4,5-tetrahydro-3,5-dioxo- 1,2,4-triazin-2-yl-phenyl)acetoni- trile	Turkeys	12 weeks	1	1	Use prohibited at least five days before slaughter.	30. 9. 1999 (⁵)	
				Chickens reared for laying	16 weeks	1	1	—	30. 9. 1999 (⁶)	
28		Maduramycin ammonium	$C_{27}H_{43}O_{17}N$ (ammonium salt of a polyether monocarboxylic acid produced by <i>Actinomadura yumaensis</i> )	Turkeys	16 weeks	5	5	Use prohibited at least five days before slaughter. Indicate in the instructions for use: — 'Dangerous for equines' — 'This feedingstuff contains an ionophore; simultaneous	30. 9. 1999 (⁵)	

## ▼ M105

Regis- tration number	Name and registration number of person responsible for marketing (1)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minim- um content		Maximum content	Other provisions	Duration of authorisation
						mg/kg complete feedingsstuff				
									use with certain medicinal substances (e.g. tiamulin) can be contra indicated*	

## C. Growth promoters

Regis- tration number	Name and registration number of person responsible for marketing (1)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minim- um content		Maximum content	Other provisions	Duration of authorisation
						mg/kg complete feedingsstuff				
—		—	—	—	—	—	—	—	—	—

(1) Authorisation linked to the person responsible with effect from 1 October 1999.

(2) First authorisation 18 July 1994, Commission Directive 94/41/EC (OJ L 209, 12. 8. 1994, p. 18).

(3) First authorisation 15 December 1997, Commission Directive 97/72/EC (OJ L 351, 23. 12. 1997, p. 55).

(4) First authorisation 21 February 1996, Commission Directive 96/77/EC (OJ L 51, 1. 3. 1996, p. 45).

(5) First authorisation 14 October 1996, Commission Directive 96/66/EC (OJ L 272, 25. 10. 1996, p. 32).

**▼ M100***ANNEX C*

## PART I

Additives subject to authorization linked to the person responsible for putting them into circulation referred to in Article 2 (aaa) of the Directive:

- antibiotics: all additives belonging to this group,
- coccidiostats and other medicinal substances: all additives belonging to this group,
- growth promoters: all additives belonging to this group.

## PART II

Other additives referred to in Article 2 (aaaa) of the Directive:

- antioxidant substances: all additives belonging to this group,
- flavouring and appetizing substances,
- emulsifying and stabilizing agents, thickeners and gelling agents: all additives belonging to this group,
- colourants, including pigments: all additives belonging to this group,
- preservatives,
- vitamins, provitamins and chemically well-defined substances having similar effect: all additives belonging to this group,
- trace elements: all additives belonging to this group,
- binders, anti-caking agents and coagulants: all additives belonging to this group,
- acidity regulators: all additives belonging to this group,
- enzymes: all additives belonging to this group,
- micro-organisms: all additives belonging to this group.



## ANNEX I

## TABLE OF CORRESPONDANCE

Directive 70/524	Present Directive
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
Article 5	Article 5
Article 6	Article 6
Article 7	Article 7
Article 7a	Article 7a
Article 8	Article 8
Article 9	Article 9
Article 10	Article 10
Article 11	Article 11
Article 12	Article 12
Article 13	Article 13
Article 14	Article 14
Article 15	Article 15
Article 16	Article 16
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Article 20	Article 20
Article 21	Article 21
Article 22	Article 22
Article 23	Article 23
Article 24	Article 24
Article 25	Article 25
Article 26	Article 26
Article 27	Article 27
-	ANNEX I