1982 No. 258

FOOD AND DRUGS

Composition and Labelling

Miscellaneous Additives in Food (Amendment) Regulations (Northern Ireland) 1982

Made . . . . . *9th August 1982*

Coming into operation . . . *20th September 1982*

The Department of Health and Social Services(**a**) in exercise of the powers conferred on it by sections 4, 7, 68 and 68A(**b**) of the Food and Drugs Act (Northern Ireland) 1958(**c**) and of every other power enabling it in that behalf, and after consultation in accordance with section 68(2) with such organisations as appear to it to be representative of interests substantially affected by these regulations, hereby makes the following regulations:

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Miscellaneous Additives in Food (Amendment) Regulations (Northern Ireland) 1982 and shall come into operation on 20th September 1982.

(2) In these regulations "the principal regulations" means the Miscellaneous Additives in Food Regulations (Northern Ireland) 1981(**d**).

Amendment of the principal regulations

2. Regulation 2(1) of the principal regulations shall be amended—

(*a*) by inserting after the definition of "buffer" the following definition:—

"'bulking aid' means any substance, other than air, water or chewing gum base, which is capable, and generally used for the purpose, of—

(*a*) contributing to the bulk of food without contributing significantly to its available energy value, or

(*b*) producing bulk upon ingestion;';

(*b*) by inserting after the definition of "container" the following definition:—

"'dietetic food' means any food which—

(*a*) has been specially made for a class of persons whose digestive process or metabolism is disturbed or who, by reason of their special physiological condition, obtain special benefit from a controlled consumption of certain substances, and

(*b*) is suitable for fulfilling the particular nutritional requirements of that class of persons;';

(*c*) by inserting after the definition of "firming agent" the following definition:—

"'flavour modifier' means any substance which is capable of enhancing, reducing or otherwise modifying the taste or odour, or both, of a food, but does not include enzymes or water or any substance primarily used to impart taste or odour, or both, to a food;';

(**a**) *See* S.R. & O. (N.I.) 1964 No. 205 art. 5 and Sch. 2 Part.I and 1973 c. 36s. 40 and Sch. 5 para. 8

(**b**) Added by S.R. & O. (N.I.) 1972 No. 363

(**c**) 1958 c. 27 (N.I.)

(**d**) S.R. 1981 No. 193, to which there is an amendment not relevant to these regulations

(*d*) by inserting after the definition of "Food Chemicals Codex 1972" the following definition:—

"'Food Chemicals Codex 1981" means the edition of the Food Chemicals Codex published in 1981 by the National Academy Press, Washington DC, United States of America;';

(*e*) by inserting in the definition of "miscellaneous additive" after the word "buffer" the words "bulking aid,";

(*f*) by inserting in the definition of "miscellaneous additive" after the words "firming agent" the words "flavour modifier".

3. Regulation 4 of the principal regulations shall be amended:—

(*a*) by substituting in regulation 4(1) for the word "additive." where it appears for the second time the following words:—

"additive:

Provided that any dietetic food may have in it or on it added L-glutamic acid, potassium hydrogen L-glutamate or calcium dihydrogen di-L-glutamate.";

(*b*) by inserting in the proviso to regulation 4(2) after the words "Provided that" the words ", subject to regulation 5A".

4. The following regulation shall be inserted after regulation 5 of the principal regulations:—

"*Food for babies and young children*

5A. A person shall not sell any food that is specially prepared for babies or young children if it has in it or on it any added 2-aminoethanol, *alpha*-cellulose, sodium hydrogen L-glutamate, guanosine 5′-(disodium phosphate), inosine 5′-(disodium phosphate), polydextrose or sodium 5′-ribonucleotide.".

5. Part 1 of Schedule 1 to the principal regulations shall be amended—

(*a*) by inserting after the item relating to adipic acid the following item:—

In column 1 (*Name of miscellaneous additive*)	In column 2 (*Serial number*)
"2-Aminoethanol	—";

(*b*) by inserting after the item relating to carnauba wax the following item:—

In column 1 (*Name of miscellaneous additive*)	In column 2 (*Serial number*)
"*Alpha*-cellulose	E460(*ii*)";

(*c*) by inserting after the item relating to calcium gluconate the following item:—

In column 1 (*Name of miscellaneous additive*)	In column 2 (*Serial number*)
"Sodium hydrogen L-glutamate	—";

(*d*) by inserting after the item relating to edible bone phosphate the following items:—

In column 1 (*Name of miscellaneous additive*)	In column 2 (*Serial number*)
"Guanosine 5′—(disodium phosphate)	—
Inosine 5′—(disodium phosphate) ...	—
Polydextrose	—
Sodium 5′—ribonucleotide	—".

6. Part II of Schedule 1 to the principal regulations shall be amended—

(*a*) by inserting after the item relating to adipic acid the following item:—

"*2-Aminoethanol*

Synonym	Monoethanolamine.
Description	Colourless or yellowish viscous hygroscopic liquid miscible with water in all proportions.
Content	Not less than 98.0 per centum of $H_2NCH_2CH_2OH$.
Water	Not more than 0.5 per centum.
Distillation Range	166°C to 176°C (at 760 mm Hg).
Ethylene oxide	Not more than 10 mg/kg.";

(*b*) by inserting after the item relating to carnauba wax the following item:—

"Alpha-*cellulose*

Synonym	Powdered cellulose.

The criteria in the monograph for cellulose, powdered, contained in the Food Chemicals Codex 1981 at page 80. Additionally the level of lead present shall not exceed 1 mg/kg.";

(*c*) by inserting in the item relating to sodium ferrocyanide immediately below the heading the following words:—

"Synonym	Sodium hexacyanoferrate (II).";

(*d*) by inserting in the item relating to potassium ferrocyanide immediately below the heading the following words:—

"Synonym	Potassium hexacyanoferrate (II).";

(*e*) by inserting after the item relating to calcium gluconate the following item:—

"*Sodium hydrogen* L-*glutamate*

Synonyms	*mono*Sodium glutamate. Sodium glutamate. Glutamic acid, sodium salt.
Formula	$C_5H_8NNaO_4.H_2O$ (molecular weight 187.13).

The criteria in the monograph for monosodium L-glutamate contained in the Food Chemicals Codex 1981 at page 203.";

(*f*) by inserting after the item relating to edible bone phosphate the following items:—

"*Guanosine 5′—(disodium phosphate)*

Synonyms	Sodium 5′—guanylate. *di*Sodium guanosine 5′—monophosphate.
Formula	$C_{10}H_{12}N_5Na_2O_8P.xH_2O$ (molecular weight (anhydrous) 407.20).

The criteria in the monograph for disodium guanylate contained in the Food Chemicals Codex 1981 at page 105.

Inosine 5′—(disodium phosphate)

Synonyms	Sodium 5′—inosinate. *di*Sodium inosine 5′—monophosphate.
Formula	$C_{10}H_{11}N_4Na_2O_8P.xH_2O$ (molecular weight (anhydrous) 392.19).

The criteria in the monograph for disodium inosinate contained in the Food Chemicals Codex 1981 at page 106.

Polydextrose

Description	Polydextrose is an off-white to light tan coloured, water-soluble powder. It consists of a randomly bonded condensation polymer produced by the reaction of D-glucose with sorbitol and citric acid. Free acid groups may be neutralised with potassium hydroxide.
Content	Not less than 90.0 per centum of polymer on an ash-free and water-free basis.
Free glucose	Not more than 4.0 per centum on an ash-free and water-free basis.
Free 1,6-anhydro-D-glucose	Not more than 4.0 per centum on an ash-free and water-free basis.
Free sorbitol	Not more than 2.0 per centum on an ash-free and water-free basis.
Water	Not more than 4.0 per centum (Karl Fischer).
pH (10.0 per centum aqueous solution)	Not less than 2.5 and not more than 3.5 (not less than 5.0 and not more than 6.0 for the neutralised product).
Sulphated ash	Not more than 0.3 per centum (not more than 3.0 per centum for the neutralised product).
Arsenic	Not more than 1 mg/kg.
Lead	Not more than 1 mg/kg.

Sodium 5′—ribonucleotide

Description	White or nearly white crystalline powder consisting of a mixture of guanosine 5′—(disodium phosphate) and inosine 5′—(disodium phosphate) in approximately equal proportions. Soluble in water, practically insoluble in ethanol.
Content	Not less than 97.0 per centum and not more than 102.0 per centum of $C_{10}H_{12}N_5Na_2O_8P$ and $C_{10}H_{11}N_4Na_2O_8P$, and not less than 47.0 per centum and not more than 53.0 per centum of $C_{10}H_{12}N_5Na_2O_8P$ or of $C_{10}H_{11}N_4Na_2O_8P$, in every case calculated on an anhydrous basis.
Moisture	Not less than 22.0 per centum and not more than 26.0 per centum (Karl Fischer).

pH (5.0 per centum aqueous solution)	Not less than 7.0 and nor more than 8.5.
Ammonium salts	Place 100 mg of sample in a test tube. Add 50 mg magnesium oxide plus 1 ml of water. Heat on a water bath for 5 minutes; the vapour evolved does not affect the colour of moist litmus paper.
Amino acids	Place 5 ml of a 0.1 per centum (weight/volume) solution in a test tube. Add 1 ml of a 2.0 per centum (weight/volume) solution of ninhydrin and heat for 3 minutes; no blue colour is produced.
Other nucleotides	The paper chromatogram obtained when sodium 5′—ribonucleotide is analysed using the procedure described for "other nucleotides" in the monograph for disodium guanylate contained in the Food Chemicals Codex 1981 at page 105 shall show no spots other than those for guanosine 5′—(disodium phosphate) and inosine 5′—(disodium phosphate).".

7. Schedule 2 to the principal regulations shall be amended by inserting after the item relating to glacé cherries the following items:—

In column 1 (*Specified food*)	In column 2 (*Permitted miscellaneous additive*)	In column 3 (*Milligrams per kilogram not exceeding-*)
"Peeled fruit	2-Aminoethanol	100
Peeled vegetables ...	2-Aminoethanol	100".

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 9th August 1982.

(L.S.) *W. Young*
Assistant Secretary

EXPLANATORY NOTE

(This note is not part of the Regulations.)

These regulations, which come into operation on 20th September 1982, amend the Miscellaneous Additives in Food Regulations (Northern Ireland) 1981 ("the principal regulations").

The regulations—

(*a*) add bulking aids and flavour modifiers to the categories of miscellaneous additive (regulation 2(*a*), (*c*), (*e*) and (*f*));

(*b*) amend the principal regulations so as to permit the sale of dietetic foods containing added L-glutamic acid, potassium hydrogen L-glutamate or calcium dihydrogen di-L-glutamate (which would otherwise be prohibited by virtue of the addition of flavour modifiers to the categories of miscellaneous additive) (regulations 2(*b*) and 3(*a*));

(*c*) add to the list of permitted miscellaneous additives in Part I of Schedule I to the principal regulations 2 — aminoethanol, *alpha*-cellulose (E460(*ii*)), sodium hydrogen L-glutamate, guanosine 5′ — (disodium phosphate), inosine 5′ — (disodium phosphate), polydextrose and sodium 5′ — ribonucleotide, prescribe specific purity criteria for those miscellaneous additives and consequently add a new definition to regulation 2(1) of the principal regulations (regulations 2(*d*), 5 and 6(*a*), (*b*), (*e*) and (*f*));

(*d*) insert a provision prohibiting the sale of food specially prepared for babies and young children which contains those permitted miscellaneous additives (regulations 3(*b*) and 4);

(*e*) amend the principal regulations so as to restrict to certain specified foods and within prescribed limits the use of 2-aminoethanol (regulation 7);

(*f*) insert in Part II of Schedule I to the principal regulations synonyms for sodium ferrocyanide and potassium ferrocyanide (regulation 6(*c*) and (*d*)).

The Food Chemicals Code 1981 referred to in regulations 2(*d*) and 6(*b*), (*e*) and (*f*) may be inspected at the British Library Lending Division, Boston Spa, Wetherby, West Yorkshire LS23 7BQ (telephone Boston Spa 843434) and by appointment at the library of the Ministry of Agriculture, Fisheries and Food at Great Westminster House, Horseferry Road, London SW1P 2AE (telephone 01-216-7591).