CODEX ALIMENTARIUS COMMISSION H







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Agenda Item 4 (a)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES

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ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES AND PROCESSING AIDS IN CODEX STANDARDS

BACKGROUND

- In accordance with the section concerning Relations between Commodity Committees and General Committees of the Codex Alimentarius Commission Procedural Manual, "All provisions in respect of food additives (including processing aids) contained in Codex commodity standards should be referred to the Committee on Food Additives, preferably before the Standards have been advanced to Step 5 of the Procedure for the Elaboration of Codex Standards or before they are considered by the commodity committee concerned at Step 7, though such referral should not be allowed to delay the progress of the Standard to the subsequent Steps of the Procedure.".
- The following food additive and processing aids provisions of Codex standards have been submitted for endorsement since the 46th Session of the Codex Committee on Food Additives and are listed by:
 - (i) Technological function, INS number and food additive name;
 - (ii) Proposed level:
 - (iii) ADI (mg additive/kg body weight per day); and
 - (iv) Notes.
- 3. The following abbreviations have been used in the preparation of this paper:
- INS International Numbering System for food additives. The INS has been prepared by the Codex Committee on Food Additives for the purpose of providing an agreed international numerical system for identifying food additives in ingredient lists as an alternative to the declaration of the specific name¹.
- Acceptable Daily Intake. An estimate of the amount of a substance in food or drinking-water, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable risk (standard human = 60 kg)². The ADI is listed in units of mg per kg of body weight.
- ADI "Not Specified". A term applicable to a food substance of very low toxicity which, on the basis of the available data (chemical, biochemical, toxicological, and other), the total dietary intake of the substance arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food does not, in the opinion of JECFA, represent a hazard to health. For that reason, and for reasons stated in individual evaluations, the establishment of an acceptable daily intake expressed in numerical form is not deemed necessary. An additive meeting this criterion must be used within the bounds of good manufacturing practice, i.e., it should be technologically efficacious and should be used at the lowest level necessary to achieve this effect, it should not conceal inferior food quality or adulteration, and it should not create a nutritional imbalance².

ADI "Not Limited". A term no longer used by JECFA that has the same meaning as ADI "not specified"².

Class Names and the International Numbering System for Food Additives (CAC/GL 36-2001)

JECFA Glossary of Terms: http://www.who.int/ipcs/food/jecfa/en/index.html.

Temporary ADI. Used by JECFA when data are sufficient to conclude that use of the substance is safe over the relatively short period of time required to generate and evaluate further safety data, but are insufficient to conclude that use of the substance is safe over a lifetime. A higher-than-normal safety factor is used when establishing a temporary ADI and an expiration date is established by which time appropriate data to resolve the safety issue should be submitted to JECFA. The temporary ADI is listed in units of mg per kg of body weight².

- **Conditional ADI.** A term no longer used by JECFA to signify a range above the "unconditional ADI" which may signify an acceptable intake when special problems, different patterns of dietary intake, and special groups of the population that may require consideration are taken into account².
- **No ADI allocated.** There are various reasons for not allocating an ADI, ranging from a lack of information to data on adverse effects that call for advice that a food additive or veterinary drug should not be used at all. The report should be consulted to learn the reasons that an ADI was not allocated².

Acceptable².

<u>Flavouring agents</u>: Used to describe flavouring agents that are of no safety concern at current levels of intake and subsequent reports of meetings on food additives). If an ADI has been allocated to the agent, it is maintained unless otherwise indicated.

<u>Enzyme preparations</u>: Used to describe enzymes that are obtained from edible tissues of animals or plants commonly used as foods or are derived from microorganisms that are traditionally accepted as constituents of foods or are normally used in the preparation of foods. Such enzyme preparations are considered to be acceptable provided that satisfactory chemical and microbiological specifications can be established.

<u>Food additives</u>: Used on some occasions when present uses are not of toxicological concern or when intake is self-limiting for technological or organoleptic reasons.

Acceptable Level of Treatment. ADIs are expressed in terms of mg per kg of body weight per day. In certain cases, however, food additives are more appropriately limited by their levels of treatment. This situation occurs most frequently with flour treatment agents. It should be noted that the acceptable level of treatment is expressed as mg/kg of the commodity. This should not be confused with an ADI².

Good Manufacturing Practice (GMP) in the Use of Food Additives ³ means that:

- the quantity of the additive added to food does not exceed the amount reasonably required to accomplish its intended physical nutritional or other technical effect in food;
- the quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technological effect in the food itself, is reduced to the extent reasonably possible;
- the additive is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient. Food grade quality is achieved by compliance with the specifications as a whole and not merely with individual criteria in terms of safety.

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³ Procedural Manual of the Codex Alimentarius Commission (Definitions)

ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES IN CODEX COMMODITY STANDARDS

33rd Session of the Committee on Fish and Fishery Products (CCFFP)

(A) Draft Standard for Fresh and Quick Frozen Raw Scallop Products⁴

- 1. In response to the comments made by the 45th CCFA in the endorsement process of the food additive provisions in the draft Standard for Fresh and Quick Frozen Raw Scallop Products (section on Quick Frozen Scallop Meat and Roe-on Scallops Processed With Phosphates), the 33rd CCFFP agreed to present the food additives in a tabular format in line with the proposal of CCFA and agreed to inform CCFA that phosphates were widely used and technologically justified for quick frozen products.
- 2. The Committee **is invited to consider for endorsement** the food additive provisions in the draft Standard for Fresh and Quick Frozen Raw Scallop Products, as presented in Annex 1.

(B) Provisions for food additives in other standards for fish and fishery products ⁵

- 3. The Committee **is invited to consider for endorsement** the revised food additive provisions, as presented in Annex 2, of the following standards:
 - Standard for Quick Frozen Shrimps or Prawns (CODEX STAN 92-1981)
 - Standard for Quick Frozen Lobsters (CODEX STAN 95-1981)
 - Standard for Quick Frozen Blocks of Fish Fillets, Minced Fish Flesh and Mixtures of Fillets and Minced Fish Flesh (CODEX STAN 165-1989)
 - Standard for Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets Breaded or in Batter (CODEX STAN 166-1989)
 - General Standard for Quick Frozen Fish Fillets (CODEX STAN 190-1995)

⁴ REP14/FFP para. 47 and Appendix III.

⁵ REP14/FFP paras 97-100, 106 and Appendix VI.

Annex 1

DRAFT STANDARD FOR FRESH AND QUICK FROZEN RAW SCALLOP PRODUCTS

4. FOOD ADDITIVES

4.1 Scallop Meat and Roe-on Scallop Meat

No food additives are permitted in the products defined in section 2.1.1 **2.1.1 Scallop Meat** and 2.1.2. **2.1.2 Roe-on Scallop Meat**

4.2 Quick Frozen Scallop Meat and Quick Frozen Roe-on Scallop Meat Processed With Phosphates

Humectant / Sequestrant				
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note
338; 339(i)-(iii); 340(i)-(iii); 341(i)-(iii); 342(i),(ii); 343(i)-(iii); 450(i)-(iii),(v)-(vii); 451(i),(ii); 452(i)-(v); 542	Phosphates	2200 mg/kg as phosphorus	A group MTDI 70 mg/kg bw as phosphorus from all food sources, (26 th JECFA, 1982)	In GSFA food category 09.2.1 "Frozen fish, fish fillet and fish products, including molluscs, crustacean and echinoderms": phosphates: ML 2 200 mg/kg (as phosphorus)

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Annex 2

FOOD ADDITIVE PROVISIONS IN STANDARDS FOR FISH AND FISHERY PRODUCTS

Note: New provisions for endorsement are presented in underlined/bold font and deletion in strikethrough font

STANDARD FOR QUICK FROZEN SHRIMPS OR PRAWNS CODEX STAN 92-1981

4. FOOD ADDITIVES

Only the use of the following additives is permitted.

New provisions for endorsement are presented in underlined/bold font and deletion in strikethrough font

Acidity Regula	Acidity Regulators				
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note	
330	Citric acid	GMP	Group ADI "Not Limited for citric acid and its calcium, potassium, sodium and ammonium salts (17 th JECFA, 1973)	GSFA Table 3	
Humectants -	Moisture/Water Retention Agents				
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note	
339(i) 339(ii) 339(iii) 340(i) 340(ii) 341(ii) 341(ii) 450(i) 450(ii) 450(v) 450(vii) 451(ii) 451(ii) 452(i) 452(ii) 452(iii)	Sodium dihydrogen phosphate Disodium hydrogen phosphate Trisodium phosphate Potassium dihydrogen phosphate Dipotassium hydrogen phosphate Tripotassium phosphate Calcium dihydrogen phosphate Calcium hydrogen phosphate Tricalcium phosphate Tricalcium diphosphate Trisodium diphosphate Tetrasodium diphosphate Tetrapotassium diphosphate Calcium dihydrogen diphosphate Pentasodium triphosphate Pentapotassium triphosphate Potassium polyphosphate Sodium calcium polyphosphate Sodium calcium polyphosphate	2200 mg/kg as phosphorus, singly or in combination	A group MTDI 70 mg/kg bw as phosphorus from all food sources, (26 th JECFA, 1982)	In GSFA food category 09.2. "Frozen fish, fish fillet and fish products, including molluses crustacean and echinoderms" phosphates: ML 2 200 mg/k (as phosphorus)	

452(iv)	Calcium polyphosphate					
452(v)	Ammonium polyphosphate					
<u>542</u>	Bone phosphate					
Antioxidants	Antioxidants					
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note		
300	Ascorbic acid (L-)	GMP				
Colours	Colours					
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note		
124	Ponceau 4R	30 mg/kg in heat-treated products only				
Preservatives						
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note		
221	Sodium sulphite	100 mg/kg in the edible part of				
223	Sodium metabisulphite	the raw product, or 30 mg/kg in				
224	Potassium metabisulphite	the edible part of the cooked				
225	Potassium sulphite	product, singly or in combination, expressed as SO2				

STANDARD FOR QUICK FROZEN LOBSTERS CODEX STAN 95-1981

4. FOOD ADDITIVES

Humectants - Moisture/Water Retention Agents				
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note
339(i)	Sodium dihydrogen phosphate			
339(ii)	Disodium hydrogen phosphate			
339(iii)	Trisodium phosphate			
340(i)	Potassium dihydrogen phosphate			In GSFA food category 09.2.1
340(ii)	Dipotassium hydrogen phosphate		A group MTDL 70 mg/kg by on	"Frozen fish, fish fillet and fish
340(iii)	Tripotassium phosphate	2200 mg/kg as phosphorus,	A group MTDI 70 mg/kg bw as phosphorus from all food	products, including molluscs,
341(i)	Calcium dihydrogen phosphate	singly or in combination	sources, (26 th JECFA, 1982)	crustacean and echinoderms":
<u>341(ii)</u>	Calcium hydrogen phosphate		Sources, (20 3EOFA, 1902)	phosphates: ML 2 200 mg/kg
341(iii)	Tricalcium phosphate		(as pho	(as phosphorus)
450(i)	Disodium diphosphate			
450(ii)	Trisodium diphosphate			
450(iii)	Tetrasodium diphosphate			

450(v)	Tetrapotassium diphosphate					
450(vii)	Calcium dihydrogen diphosphate					
451(i)	Pentasodium triphosphate					
451(ii)	Pentapotassium triphosphate					
452(i)	Sodium polyphosphate					
452(ii)	Potassium polyphosphate					
452(iii)	Sodium calcium polyphosphate					
452(iv)	Calcium polyphosphate					
<u>452(v)</u>	Ammonium polyphosphate					
<u>542</u>	Bone phosphate					
Preservatives	Preservatives					
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note		
221	Sodium sulphite	100 mg/kg in the edible part of				
223	Sodium metabisulphite	the raw product, or 30 mg/kg in	A group ADI 0-0.7 mg/kg bw as			
224	Potassium metabisulphite	the edible part of the cooked	SO ₂ for sulphites (51 st JECFA,			
225	Potassium sulphite	product, singly or in combination,	1998)			
228	Potassium bisulphite (for use in the raw product only)	expressed as SO ₂				
Antioxidants						
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note		
300	Ascorbic acid					
301	Sodium ascorbate	GMP				
303	Potassium ascorbate					

STANDARD FOR QUICK FROZEN BLOCKS OF FISH FILLET, MINCED FISH FLESH AND MIXTURES OF FILLETS AND MINCED FISH FLESH CODEX STAN 165-1989

4. FOOD ADDITIVES

Humectants -	<u>Humectants</u> – Moisture/Water Retention Agents				
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note	
339(i)	Sodium dihydrogen phosphate				
339(ii)	Disodium hydrogen phosphate			In GSFA food category 09.2.1	
339(iii)	Trisodium phosphate		A success MTDL 70 may/kg buy as	"Frozen fish, fish fillet and fish	
340(i)	Potassium dihydrogen phosphate	2200 mg/kg as phosphorus,	A group MTDI 70 mg/kg bw as phosphorus from all food sources,	products, including molluscs,	
340(ii)	Dipotassium hydrogen phosphate	singly or in combination	(26 th JECFA, 1982)	crustacean and echinoderms":	
340(iii)	Tripotassium phosphate		(20 JEOFA, 1902)	phosphates: ML 2 200 mg/kg	
341(i)	Calcium dihydrogen phosphate			(as phosphorus)	
341(ii)	Calcium hydrogen phosphate				

341(iii)	Tricalcium phosphate				
450(i)	Disodium diphosphate				
450(ii)	Trisodium diphosphate				
450(iii)	Tetrasodium diphosphate				
450(v)	Tetrapotassium diphosphate				
450(vii)	Calcium dihydrogen diphosphate				
451(i)	Pentasodium triphosphate				
451(ii)	Pentapotassium triphosphate				
452(i)	Sodium polyphosphate				
452(ii)	Potassium polyphosphate				
452(iii)	Sodium calcium polyphosphate				
452(iv)	Calcium polyphosphate				
452(v)	Ammonium polyphosphate				
<u>542</u>	Bone phosphate				
401	Sodium alginate	GMP			
<u>Antioxidants</u>	<u>Antioxidants</u>				
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note	
300	Ascorbic acid				
301	Sodium ascorbate	GMP			
303	Potassium ascorbate				
304	Ascorbyl palmitate	1 g/kg			
In Minced Fish	n Flesh Only				
Acidity Regula	ators				
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note	
330	Citric acid				
331	Sodium citrate	GMP			
332	Potassium citrate				
Thickeners					
412	Guar gum				
410	Carob bean (Locust bean) gum				
440	Pectins				
466	Sodium carboxymethyl cellulose				
415	Xanthan gum	GMP			
407	Carrageenan and its Na, K, NH4 salts (including Furcelleran)				
407a	Processed EucheumaSeaweed (PES)				
461	Methyl cellulose				

STANDARD FOR QUICK FROZEN FISH STICKS (FISH FINGERS), FISH PORTIONS AND FISH FILLETS - BREADED OR IN BATTER CODEX STAN 166 – 1989

4. FOOD ADDITIVES

Humecta	Humectants - Moisture/Water Retention Agents				
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note	
339(i)	Sodium dihydrogen phosphate				
339(ii)	Disodium hydrogen phosphate				
339(iii)	<u>Trisodium phosphate</u>				
340(i)	Potassium dihydrogen phosphate				
340(ii)	Dipotassium hydrogen phosphate				
340(iii)	<u>Tripotassium phosphate</u>				
341(i)	Calcium dihydrogen phosphate				
341(ii)	Calcium hydrogen phosphate				
341(iii)	Tricalcium phosphate	2200 mg/kg as phosphorus, singly or in combination		In GSFA food category 09.2.2 "Frozen battered fish, fish fillet and fish products, including molluscs, crustacean and echinoderms": phosphates: ML 2 200 mg/kg (as phosphorus)	
<u>450(i)</u>	Disodium diphosphate		A group MTDL 70 mg/kg by as		
450(ii)	Trisodium diphosphate		A group MTDI 70 mg/kg bw as phosphorus from all food sources, (26 th JECFA, 1982)		
450(iii)	Tetrasodium diphosphate				
450(v)	Tetrapotassium diphosphate				
450(vii)	Calcium dihydrogen diphosphate				
451(i)	Pentasodium triphosphate				
451(ii)	Pentapotassium triphosphate				
452(i)	Sodium polyphosphate				
452(ii)	Potassium polyphosphate				
452(iii)	Sodium calcium polyphosphate				
452(iv)	Calcium polyphosphate				
452(v)	Ammonium polyphosphate				
<u>542</u>	Bone phosphate				
401	Sodium alginate	GMP			
Antioxida	ants				
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note	
300	Ascorbic acid				
301	Sodium ascorbate	GMP			
303	Potassium acerbate				
304	Ascorbyl palmiatate	1 g/kg			

In Addition	on, for Minced Fish Flesh Only					
Acidity R	egulators					
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note		
330	Citric acid					
331	Sodium citrate	GMP				
332	Potassium citrate					
Thickene	ers					
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note		
412	Guar gum					
410	Carob bean (Locust bean) gum					
440	Pectins					
466	Sodium carboxymethyl cellulose	GMP				
415	Xanthan gum	GIVIF				
407	Carrageenan and its Na, K, NH4salts (including Furcelleran)					
407a	Processed Eucheuma Seaweed (PES)					
461	Methyl cellulose					
Food Additives for Breaded or Batter Coatings						
Raising A	Agents					
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note		
339(i)	Sodium dihydrogen phosphate					
340(iii)	<u>Tripotassium phosphate</u>					
341(i)	Calcium dihydrogen phosphate					
341(ii)	Calcium hydrogen phosphate					
341(iii)	Tricalcium phosphate					
450(i)	Disodium diphosphate					
450(ii)	Trisodium diphosphate	440 mg/kg as phaspharus	A group MTDI 70 mg/kg bw as			
450(iii)	Tetrasodium diphosphate	440 mg/kg as phosphorus, singly or in combination	phosphorus from all food sources,			
450(v)	Tetrapotassium diphosphate	singly of in combination	(26 th JECFA, 1982)			
450(vi)	Dicalcium diphosphate					
450(vii)	Calcium dihydrogen diphosphate					
452(i)	Sodium polyphosphate					
452(ii)	Potassium polyphosphate					
452(iii)	Sodium calcium polyphosphate					
452(iv)	Calcium polyphosphate					
541	Sodium aluminium phosphate, basic and acidic					
500	Sodium carbonates					
501	Potassium carbonates	GMP				
503	Ammonium carbonates					
500	Flavour Enhancers					

INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note
621	Monosodium glutamate	CMD		
622	Monopotassium glutamate	GMP		
Colours				
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note
160b(i)	Annatto extracts bixin-based			
160b(ii)	Annatto extract (norbixin-based)			
150a	Caramel I (plain)			
160a(i)	β-carotene (Synthetic)			
160e	β-apo-carotenal			
Thickene	ers			
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	
412	Guar gum			
410	Carob bean (Locust bean) gum			
440	Pectins			
466	Sodium carboxymethyl cellulose			
415	Xanthan gum			
407	Carrageenan and its Na, K, NH ₄ salts (including Furcelleran)			
407a	Processed EuchemaSeaweed (PES)			
461	Methyl cellulose			
<u>400</u>	Alginic acid	GMP	An ADI "not specified" (39 th JECFA, 1992)	GSFA Table 3
401	Sodium alginate	GIVIF	·	
402	Potassium alginate		An ADI "not specified" (39 th JECFA, 1992)	GSFA Table 3
<u>403</u>	Ammonium alginate		An ADI "not specified" (39 th JECFA, 1992)	GSFA Table 3
<u>404</u>	Calcium alginate		An ADI "not specified" (39 th JECFA, 1992)	GSFA Table 3
463	Hydroxypropyl cellulose			
464	Hydroxypropyl methylcellulose			
465	Methylethylcellulose			

Emulsifie	<u>Emulsifiers</u>				
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)		
471	Monoglycerides of fatty acids	GMP			
322	Lecithins	GWF			
Modified	Starches				
1401	Acid treated starches				
1402	Alkaline treated starches				
1404	Oxidized starches				
1410	Monostarch phosphate				
1412	Distarch phosphate esterified with sodium trimetaphosphate; esterified with phosphorus oxychloride				
1414	Acetylated distarch phosphate	GMP			
1413	Phosphated distarch phosphate				
1420	Starch acetate esterified with acetic anhydride				
1421	Starch acetate esterified with vinyl acetate				
1422	Acetylated distarch adipate				
1440	Hydroxypropyl starch				
1442	Hydroxypropyl starch phosphate				

GENERAL STANDARD FOR QUICK FROZEN FISH FILLETS (CODEX STAN 190-1995)

4. FOOD ADDITIVES

Humectants -	Moisture/Water Retention Agents			
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note
339(i)	Sodium dihydrogen phosphate			
339(ii)	Disodium hydrogen phosphate			
339(iii)	Trisodium phosphate			
340(i)	Potassium dihydrogen phosphate			
340(ii)	Dipotassium hydrogen phosphate			In GSFA food category 09.2.1
340(iii)	Tripotassium phosphate	2200	A group MTDI 70 mg/kg bw as	"Frozen fish, fish fillet and fish
341(i)	Calcium dihydrogen phosphate	2200 mg/kg as phosphorus, singly or in combination	phosphorus from all food sources, (26 th JECFA, 1982)	products, including molluscs, crustacean and echinoderms":
341(ii)	Calcium hydrogen phosphate	singly or in combination	sources, (26 th JECFA, 1982)	phosphates: ML 2 200 mg/kg
341(iii)	Tricalcium phosphate			(as phosphorus)
450(i)	Disodium diphosphate			(as priospriorus)
450(ii)	Trisodium diphosphate			
450(iii)	Tetrasodium diphosphate]		
450(v)	Tetrapotassium diphosphate			

450(vii)	Calcium dihydrogen diphosphate			
451(i)	Pentasodium triphosphate			
451(ii)	Pentapotassium triphosphate			
452(i)	Sodium polyphosphate			
452(ii)	Potassium polyphosphate			
452(iii)	Sodium calcium polyphosphate			
452(iv)	Calcium polyphosphate			
452(v)	Ammonium polyphosphate			
<u>542</u>	Bone phosphate			
401	Sodium alginate	GMP		
Antioxidants				
INS Number	Additive Name	Maximum Level in Product	ADI (mg/kg bw)	Note
301	Sodium ascorbate	GMP		
303	Potassium ascorbate	GMP		