CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 9a **CX/RVDF 13/21/10**

August 2013

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-first Session

Minneapolis, Minnesota, United States of America, 26 – 30 August 2013

DRAFT PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR RE-EVALUATION BY JECFA (REPLIES TO CL 2012/30-RVDF)

Replies of Brazil, Costa Rica, Peru and Philippines

BRAZIL

Brazil will not propose any veterinary drug to be included into the priority list, since at this time we were unable to collect sufficient/adequate data from publicly available information for a JECFA review of the ADI and MRLs for ivermectin.

COSTA RICA

Our country's position has been consistent in that one of the requirements limiting the recommendation for inclusion of a compound to the list of priorities is that the proponent country must submit the compound's scientific studies for evaluation. However, this is often not possible for some countries.

Nevertheless, Costa Rica would like to re-submit its request to include the assessment of MRLs for invermectin in bovine muscle tissue. Furthermore, it believes that the studies provided with the previous evaluation for this substance has the data needed to make a recommendation for MRLs in muscle of this species.

It is important to note that this drug is widely used in Latin America; international cattle trade has increased and, one of the major trade products is muscle tissue (meat). The main trade constraint is that it does not have a Codex Alimentarius reference value and thus threatens consumer health and international trade.

PERU

The Technical Commission on Residues of Veterinary Drugs does not have any comments to CL 2012/30-RVDF "Request for comments and information on the Priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA", considering that the drugs proposed by the Commission are already included in the priority list of veterinary drugs to be evaluated or re-evaluated by JECFA.

SPECIFIC COMMENTS: In the format presented in the Appendix "Recommended information to be included in the Priority List of Codex Committee on Veterinary Drugs in Foods", "Administrative Information" should include a point about "Reporting Country"; and under section "Risk Profile Elements" add a point on "Product Safety to Public Health Technical Evaluation, based on the best scientific data".

PHILIPPINES

(PRELIMINARY INFORMATION ON ETHOXYQUIN)

A) Volume of production and consumption in individual countries and volume and pattern of trade between countries

According to FAO data aquaculture production has an increasing rate of production each year as indicated in Table 1 where production in 2006 totaled to 47.3 million tons increased to 63.6 million tons. However, there is also a tremendous increase in the consumption of fish for both captured and cultured produced as shown in Table I .

Table 1
World fisheries and aquaculture production and utilization

	2006	2007	2008	2009	2010	2011
	(Million tonnes)					
PRODUCTION						
Capture						
Inland	9.8	10.0	10.2	10.4	11.2	11.5
Marine	80.2	80.4	79.5	79.2	77.4	78.9
Total capture	90.0	90.3	89.7	89.6	88.6	90.4
Aquaculture						
Inland	31.3	33.4	36.0	38.1	41.7	44.3
Marine	16.0	16.6	16.9	17.6	18.1	19.3
Total aquaculture	47.3	49.9	52.9	55.7	59.9	63.6
TOTAL WORLD FISHERIES	137.3	140.2	142.6	145.3	148.5	154.0
UTILIZATION						
Human consumption	114.2	117.2	119.7	122.6	128.2	130.8
Non-food uses	23.0	23.0	22.9	21.8	20.2	23.2
Population (billions)	6.6	6.7	6.7	6.8	6.9	7.0
Per capita food fish supply (kg)	17.4	17.6	17.8	18.1	18.6	18.8

Notes: Excluding aquatic plants. Totals may not match due to rounding. Data for 2011 are provisional estimates.

The tables 5 and 6 **shows the countries and volume of production by region including the percentage of world total production**.

Table 5

Aquaculture production by region: quantity and percentage of world total production

Selected groups and countries		1970	1980	1990	2000	2009	2010
Africa	(tonnes)	10 271	26 202	81 015	399 676	991 183	1 288 320
	(percentage)	0.40	0.60	0.60	1.20	1.80	2.20
Sub-Saharan Africa	(tonnes)	4 243	7 048	17 184	55 690	276 906	359 790
	(percentage)	0.20	0.10	0.10	0.20	0.50	0.60
North Africa	(tonnes)	6 028	19 154	63 831	343 986	714 277	928 530
	(percentage)	0.20	0.40	0.50	1.10	1.30	1.60
Americas	(tonnes)	173 491	198 850	548 479	1 423 423	2 512 829	2 576 428
	(percentage)	6.80	4.20	4.20	4.40	4.50	4.30
Caribbean	(tonnes)	350	2 329	12 169	39 704	42 514	36 871
	(percentage)	0.00	0.00	0.10	0.10	0.10	0.10
Latin America	(tonnes)	869	24 590	179 367	799 234	1 835 888	1 883 134
	(percentage)	0.00	0.50	1.40	2.50	3.30	3.10
North America	(tonnes)	172 272	171 931	356 943	584 495	634 427	656 423
	(percentage)	6.70	3.70	2.70	1.80	1.10	1.10
Asia	(tonnes)	1 799 101	3 552 382	10 801 356	28 422 189	49 538 019	53 301 157
	(percentage)	70.10	75.50	82.60	87.70	88.90	89.00
Asia (excluding China and Near East)	(tonnes)	1 034 703	2 222 670	4 278 355	6 843 429	14 522 862	16 288 881
	(percentage)	40.30	47.20	32.70	21.10	26.10	27.20
China	(tonnes)	764 380	1 316 278	6 482 402	21 522 095	34 779 870	36 734 215
	(percentage)	29.80	28.00	49.60	66.40	62.40	61.40
Near East	(tonnes)	18	13 434	40 599	56 665	235 286	278 061
	(percentage)	0.00	0.30	0.30	0.20	0.40	0.50
Europe	(tonnes)	575 598	916 183	1 601 524	2 050 958	2 499 042	2 523 179
	(percentage)	22.40	19.50	12.20	6.30	4.50	4.20
European Union (27)	(tonnes)	471 282	720 215	1 033 982	1 395 669	1 275 833	1 261 592
	(percentage)	18.40	15.30	7.90	4.30	2.30	2.10
Non-European-Union countries	(tonnes)	26 616	38 594	567 667	657 167	1 226 625	1 265 703
	(percentage)	1.00	0.80	4.30	2.00	2.20	2.10
Oceania	(tonnes)	8 421	12 224	42 005	121 482	173 283	183 516
	(percentage)	0.30	0.30	0.30	0.40	0.30	0.30
World	(tonnes)	2 566 882	4 705 841	13 074 379	32 417 738	55 714 357	59 872 600

Notes: Data exclude aquatic plants and non-food products. Data for 2010 for some countries are provisional and subject to revisions. Production values for 1980 for Europe include the former Soviet Union.

Table 6
Top ten regional and world aquaculture producers in 2010

Africa	Tonnes	Percentage
Egypt	919 585	71.38
Nigeria	200 535	15.57
Uganda	95 000	7.37
Kenya	12 154	0.94
Zambia	10 290	0.80
Ghana	10 200	0.79
Madagascar	6 686	0.52
Tunisia	5 424	0.42
Malawi	3 162	0.25
South Africa	3 133	0.24
Other	21 950	1.70
Total	1 288 320	100

America	Tonnes	Percentage
Chile	701 062	27.21
United States of America	495 499	19.23
Brazil	479 399	18.61
Ecuador	271 919	10.55
Canada	160 924	6.25
Mexico	126 240	4.90
Peru	89 021	3.46
Colombia	80 367	3.12
Cuba	31 422	1.22
Honduras	27 509	1.07
Other	113 067	4.39
Total	2 576 428	100

Asia	Tonnes	Percentage
China	36 734 215	68.92
India	4 648 851	8.72
Viet Nam	2 671 800	5.01
Indonesia	2 304 828	4.32
Bangladesh	1 308 515	2.45
Thailand	1 286 122	2.41
Myanmar	850 697	1.60
Philippines	744 695	1.40
Japan	718 284	1.35
Republic of Korea	475 561	0.89
Other	1 557 588	2.92
Total	53 301 157	100

Europe	Tonnes	Percentage
Norway	1 008 010	39.95
Spain	252 351	10.00
France	224 400	8.89
United Kingdom	201 091	7.97
Italy	153 486	6.08
Russian Federation	120 384	4.77
Greece	113 486	4.50
Netherlands	66 945	2.65
Faroe Islands	47 575	1.89
Ireland	46 187	1.83
Other	289 264	11.46
Total	2 523 179	100

Oceania	Tonnes	Percentage
New Zealand	110 592	60.26
Australia	69 581	37.92
Papua New Guinea	1 588	0.87
New Caledonia	1 220	0.66
Fiji	208	0.11
Guam	129	0.07
Vanuatu	105	0.06
French Polynesia	29	0.02
Northern Mariana Islands	24	0.01
Palau	12	0.01
Other	19	0.01
Total	183 516	100

World	Tonnes	Percentage
China	36 734 215	61.35
India	4 648 851	7.76
Viet Nam	2 671 800	4.46
Indonesia	2 304 828	3.85
Bangladesh	1 308 515	2.19
Thailand	1 286 122	2.15
Norway	1 008 010	1.68
Egypt	919 585	1.54
Myanmar	850 697	1.42
Philippines	744 695	1.24
Other	7 395 281	12.35
Total	59 872 600	100

Note: Data exclude aquatic plants and non-food products. Data for 2010 for some countries are provisional and subject to revisions.

Production varies from country to country, while others have small production some country have and surplus which goes to international market. Please Figure 21 .

Figure 21

World fisheries production and quantities destined for export

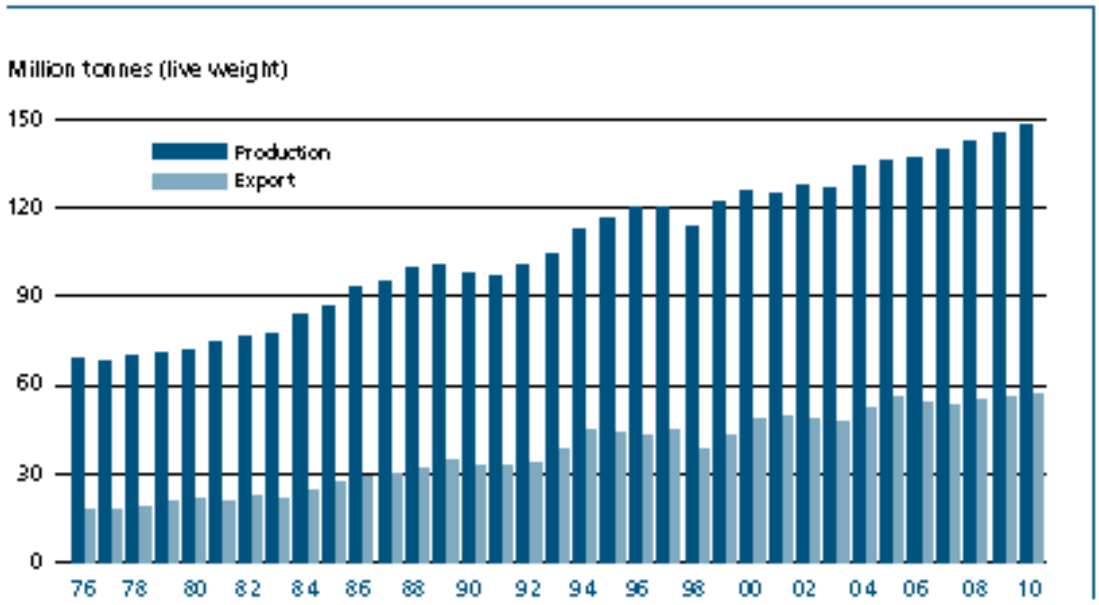


Table 12 which shows top ten exporters and importers of fish and fishery products

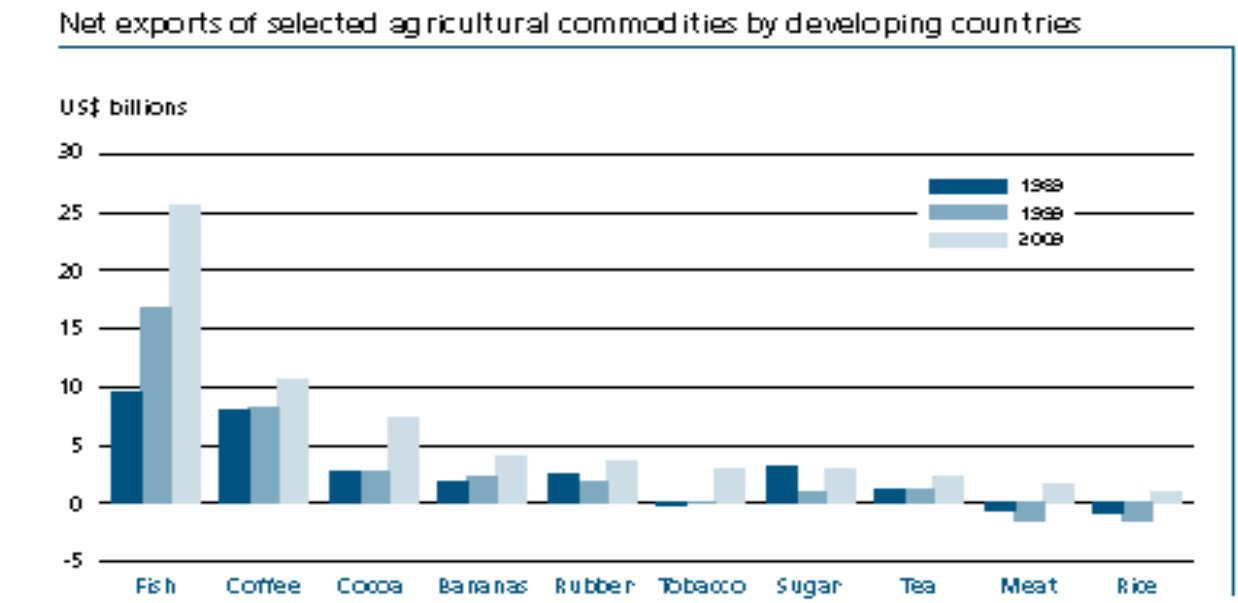
Table 12
Top ten exporters and importers of fish and fishery products

	2000	2010	APR
	(US$ million)		(Percentage)
EXPORTERS			
China	3 603	13 268	13.9
Norway	3 533	8 817	9.6
Thailand	4 367	7 128	5.0
Viet Nam	1 481	5 109	13.2
United States of America	3 055	4 661	4.3
Denmark	2 756	4 147	4.2
Canada	2 818	3 843	3.1
Netherlands	1 344	3 558	10.2
Spain	1 597	3 396	7.8
Chile	1 794	3 394	6.6
TOP TEN SUBTOTAL	26 349	57 321	8.1
REST OF WORLD TOTAL	29 401	51 242	5.7
WORLD TOTAL	55 750	108 562	6.9
IMPORTERS			
United States of America	10 451	15 496	4.0
Japan	15 513	14 973	-0.4
Spain	3 352	6 637	7.1
China	1 796	6 162	13.1
France	2 984	5 963	7.2
Italy	2 535	5 449	8.0
Germany	2 262	5 037	8.3
United Kingdom	2 184	3 702	5.4
Sweden	709	3 316	16.7
Republic of Korea	1 385	3 193	8.7
TOP TEN SUBTOTAL	26 349	69 949	10.3
REST OF WORLD TOTAL	33 740	41 837	2.2
WORLD TOTAL	60 089	111 786	6.4

Note: APR refers to the average annual percentage growth rate for 2000–2010.

Figure 23 shows that the most traded commodity is fish compared to other commodities like coffee, cocoa, bananas and others

Figure 23



The data shows that fish which includes aquacultured products has a lot of trade potential as annual production is steadily 137-154 million metric tons compared to capture fisheries which yield .4 million metric tons increase from 90.0 in 2006 to 90.4.

B) <u>Diversification of national legislation on the use of Ethoxyquin and apparent resultant or potential impediments to international trade</u>

B.1 ETHOXYQUIN AS ANTI-OXIDANT

Ethoxyquin as an antioxidant and is in the list of additives authorized for an unlimited period in the European Union. EQ with the chemical formula of 1,2,dihydro-6ethoxy 2 2 4 trimethylquinoline, with registration number of E324 is approved for all species or categories of animal at 150 mg/kg.

In the USA, the U.S. Food and Drug Administration permits the use of ethoxyquin (1,2 dihydro-6-ethoxy-2,2,4- trimethy quinoline) at 150 ppm in finished feed:

Ethoxyquin is used primarily, under Food and Drug Administration regulation 21 CFR § 172.140, as a preservative in animal feed for stabilizing fat soluble vitamins (such as vitamins A and E) to maintain the quality of feed.

1. C**hemical Identification -**Common Name: Ethoxyquin

Table 1. Ethoxyquin Structure and Nomenclature	
Empirical Formula	C14H19NO
Molecular Weight	217.34
Common name	Ethoxyquin
IUPAC name	1,2-dihydro-2,2,4-trimethylquinolin-6-yl ethyl ether
CAS name	6-ethoxy-1,2-dihydro-2,2,4-trimethylquinoline
CAS Registry Number	91-53-2
PC Code	55501
End-use product/EP	Deccoquin, Pear Wrap I, Pear Wrap III
Chemical Class	Quinoline
Known Impurities of Concern	None

A metabolic pathway of ethoxyquin in livestock was not established, despite it being use as an antioxidant and is in the list of additives authorized for an unlimited period in the European Union. ETOH with the chemical formula of 1,2,dihydro-6ethoxy 2 2 4 trimethylquinoline, with registration number of E324 is approved for all species or categories of animal at 150 mg/kg. **Also In the USA, t**he U.S. Food and Drug Administration permits the use of ethoxyquin (1,2 dihydro-6-ethoxy-2,2,4- trimethy quinoline) at 150 ppm in finished feed:

B.2 Evidence of Impediments may be provided as Quantitative Information on Volume and/or Frequency of Rejection of Consignments, as Expressed, for Example, as absolute numbers or as Rates of Rejection.

Philippines

This in reference with the policy of Japan regarding the level of ethoxyquin on the shrimp meat import from the Philippines November 12 2012 shipment of shrimp detected with 0.02 ppm ethoxyquin were returned back to the Philippines amounting to approximately 5M pesos. At present, the shrimp exports from the Philippines has a mandatory 100% testing for presence of Ethoxyquin

Vietnam

Saigon Times Shrimp exports to South Korea face ethoxyquin tests Thursday, March 21,2013,21:16 (GMT+7)

HCMC – South Korea, a big market for Vietnam's shrimp in Asia, will test the ethoxyquin contents in shrimp shipments from now until the year-end.

According to the National Agro-Forestry-Fisheries Quality Assurance Department (Nafiqad), Vietnam's shrimp exports to South Korea will undergo the ethoxyquin test in one year. The level permitted by South Korea's Animal, Plant and Fisheries Quarantine and Inspection Agency (QIA) is 0.01mg/kg, equivalent to Japan's standard. Speaking to the Daily, Truong Dinh Hoe, general secretary of the Vietnam Association of Seafood Producers and Processors (Vasep), said that the decision about the ethoxyquin tests was made as many South Korean firms also processed shrimps imported from Vietnam before exporting them to Japan. Therefore, the ethoxyquin tests are imposed on Vietnam's shrimp exports to avoid potential difficulties of South Korean firms in the Japanese market. Regarding the Japanese market, there were 30 local firms detected violating the antibiotic residues from June 12, 2012 to February 7, 2013.

However, according to Nafiqad's Document 421 sent to seafood firms, South Korea did not say how many shrimp shipments from Vietnam would be tested. Previously, with the ethoxyquin residues, Japan at first tested 30% and then 100% of Vietnam's shrimp export batches.

Currently, shrimp export to Japan is still in difficulty due to the tests although the Ministry of Agriculture and Rural Development has worked with Japan for several times to address the problem. In addition, Vietnam's shrimps are facing a risk of anti-subsidy tax in the U.S. market.

Difficulties in the importing markets may make the fishery export target of US$6.5 billion set by the ministry unobtainable. According to Vasep, seafood export in the year's first two months dropped by 0.6% to US$779 million, with shipments to the U.S. declining by nearly 10%, EU 33%, Japan 33%, Mexico 55% and China 23.5%.

VIETNAMESE SHRIMP EXPORTS TO BE TESTED FOR ETHOXYQUIN BY S. KOREA SOURCE: XINHUA TIME: 2013-APR-7 16:11

HANOI, April 5 (Xinhua) -- Vietnam's shrimp exports will be tested for Ethoxyquin by South Korea, one of Vietnam's biggest shrimp importers in Asia, local media reported on Friday.

State-run Vietnam News quoted a decision by the South Korea's Animal, Plant and Fisheries Quarantine and Inspection Agency as saying that the agency would run Ethoxyquin checks on frozen shrimp imports from Vietnam in 2013, with a permissible limit of 0. 01 ppm.

Ethoxyquin is a substance used to preserve fish meat, and most countries apply a maximum residue limit of 77-150 ppm.

According to Vietnamese shrimp exporters, the S. Korea market has similar taste to Japan and is considered as a safe-haven for Vietnamese seafood exporters when exports to Japan decreased due to Japan's strict checks on Ethoxyquin level applied since May last year.

In 2012, S. Korea ranked fifth among Vietnam's largest shrimp importers, with an import value at 171.1 million U.S. dollars, up 8.8 percent year on year. Meanwhile, shrimp exports to other markets decreased, including those to the EU (down 24.5 percent) and the United States (down 18.6 percent).

In the first three months this year, Vietnam earned about 400 million dollars from shrimp exports, a decrease of 8 percent year on year. Shrimp shipments to 10 major markets decreased, including those to Japan (down 40 percent), the EU (down 33.5 percent), and S. Korea (down 50.2 percent).

SOUTHERN SHRIMP ALLIANCE: WWW.**SHRIMP**ALLIANCE.COM/.../KNOW-YOUR-SUPPLIER-CONTINUED-**ETHOXYQUI**

Japan rejected seventeen shipments of shrimp – constituting over 18% of all food products rejected by Japan in September. Each of the seventeen shipments originated in either India or Vietnam.

Fifteen of the seventeen shipments were rejected for the presence of ethoxyquin. Similarly, in August Japan had refused another eleven shipments of shrimp from India and Vietnam for ethoxyquin. Press reports indicate that Vietnamese and Indian shrimp exports to Japan are down substantially because of these refusals. Without a major market, shrimp produced in these countries is likely to end up in markets with far greater tolerance for ethoxyquin, like the European Union and the United States.

D) Amenability of the commodity to standardisation (Information should be provided on: which quality factors are essential for the identity of the product e.g. definition, composition, etc.)

D.1 Ethoxyquin as fungicide

Data from FAO Plant Production And Protection Paper193. 2009. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide ResiduesRome, Italy, 9–18 September 2008

D.2 Residue and Analytical Aspects

Ethoxyquin was reviewed by JMPR in 1999 under the periodic review programme. At the time the Meeting made no maximum residue level recommendation for pears due to uncertainty on the toxicity of the degradation products. The 2005 JMPR established an ARfD for ethoxyquin and noted that both the ARfD and the ADI were defined in terms of the parent and metabolites/degradates methylethoxyquin (MEQ), dihydroethoxyquin (DHEQ) and dehydromethylethoxyquin (DHMEQ).

D.3 Methods of Analysis

Available analytical methods determine only parent ethoxyquin. There are no methods for the routine determination of MEQ, DHEQ and DHMEQ as needed for dietary risk assessment. Previously reviewed studies (JMPR 1999) indicated there was up to a 60% conversion of radiolabelled ethoxyquin to the metabolites/degradates, including MEQ, DHEQ and DHMEQ. This occurred over a 33 week storage interval at –2 °C.

The Meeting concluded that total residues, for dietary intake assessment, may be estimated by multiplying the measured ethoxyquin residue by a factor of 2.5. This reflects the result of the radiolabelled degradation study and typical cold storage conditions for treated pears.

D.4 Stability of pesticide residues in stored analytical samples

Ethoxyquin on pears is unstable under conditions of frozen storage at –20 °C in plastic. The apparent concentration of ethoxyquin drops to 33% of the applied dose within one day, but returns to or exceeds 100% over the next 40 days. This may have been due to an interaction between the plastic container and ethoxyquin.

Ethoxyquin on pear is somewhat more stable when stored wrapped in foil in evacuated bags at –20 °C.

The Meeting concluded that pear samples being tested for ethoxyquin should be stored frozen and protected from oxygen to the extent possible. Pears should be prepared for analysis in as short a time as possible following collection.

D.5 Results of supervised residue trials on crops

Pear

The Meeting received studies of the post-harvest treatment of pears by spraying, a combination of spraying and wrapping in treated paper, and by thermofogging. Twelve trials were conducted at the maximum USA GAP (Ethoxyquin EC, 2700 mg ai/L, brush or spray application). Residues in ranked order were: 1.6, 1.7 (2), 1.8 (2), 1.9, 2.0 (2), 2.2, 2.3 (2), 2.4 mg/kg. Four trials were conducted at the maximum USA GAP (18% ethoxyquin, thermofog application, 16.2 g ai/1000 kg). Residues in ranked order were: < 0.3 (4) mg/kg.