

SCIENTIFIC / TECHNICAL REPORT submitted to EFSA

Survey on use of veterinary medicinal products in third countries¹

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Abstract

Two separate surveys have been conducted in order assist with an evaluation of veterinary medicinal product use in third countries.

The first survey produced data on the volume (metric tonnage) of products of animal origin that were imported into the EU from Third (i.e. non-EU) countries during a seven-year period between 2002 and 2008. These data, from a total of 207 Third countries, were used to identify which countries export the most animal products to the EU. This trade information was also sub-divided into the different types of animal products being exported to the EU e.g. bovine tissues, poultry, fish, crustaceans and honey.

In the second survey, data on the therapeutic and/or prophylactic use of veterinary medicines in food producing animals in Third countries was sought. This study was designed to collect data on chemically active compound(s) within each authorised veterinary medicinal product, along with information on dosing regimes and, where available, Maximum Residue Limits (MRLs). A number of separate attempts were also made to obtain sales volumes for each authorised medicine, but these commercially sensitive data were often unavailable. All Third country data was compared to current EU legislation and, in particular, Regulation (EC) No 470/2009, laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin. This assessment identified 95 veterinary medicines that are either authorised or have MRLs in one or more Third countries, but which are not available for use within the EU. The classes of these medicines are widespread and include antibiotics, coccidiostats and a number of growth promoters.

Additional project data are available to authorised users from the bespoke project website (www.vetdrugscan.eu). These data are fully searchable by (i) Third country and (ii) types of animal products and this system has the potential for this “live” information to be regularly updated.

¹ CFP/EFSA/CONTAM/2008/02. Accepted for Publication on 24 November 2009.

Summary

The main objective of this project was to conduct a thorough review, collation and analysis of available information in order to provide a detailed overview of pharmacologically active substances of veterinary medicinal products authorised for therapeutic and/or prophylactic use in food producing animals including farmed fish and other seafood in Third (or non-EU) countries. This review was to exclude those veterinary medicines already authorised for use in the European Union [i.e. those not listed in Annex I, II or III of Regulation (EEC) 2377/90²].

The outputs from this project are as follows:

A) Import statistics for foodstuffs of animal origin from food-producing animals including farmed fish and other seafood, which are exported by Third countries into the European Union in major quantities, were obtained from an EU Trade website³ and analysed. These trade data, which cover 207 Third countries, are presented in accordance with the European Union customs codes (TARIC⁴) and are arranged by exporting country. In addition, to accommodate an additional request by EFSA, all of these trade data have been categorised according to the most analogous food classification code used for the DATEX (Data Collection and Exposure)⁵ system. These data show that, for all types of food of animal origin, the top ten Third countries which export to the EU account for over 70% of the total trade volume. Norway is the largest exporter of animal products to the EU (14.1%), followed by Brazil (10.2%), New Zealand (7.6 %), Argentina (6.9 %), China (6.2 %), United States (6.2 %), Iceland (4.4 %), Russian Federation (2.7 %), Vietnam (2.5 %) and India (2.4 %)]⁶. Of course, the exact type of product traded by each of these countries can be quite different. For example, the main imported product into the EU from Norway is fish, whereas Brazil is the major supplier of beef and poultry. Fully searchable annual export data from each Third country to the EU (and *visa versa*) between 2002 and 2008 are available to authorised users at www.vetdugscan.eu (though lack of detailed data for some TARIC sub-codes on the Export Help Desk web-site prior to 2007 are consequently absent from the vetdugscan website).

B) Chief Veterinary Officer(s) and/or licensing authorities in each Third Country listed were contacted for detailed information on authorised veterinary medicinal products that are available for use in their respective countries. Information, by animal species, was requested on:

² Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. This was replaced during the life of this project by Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009, laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council). OJ L 152, 16.6.2009 p. 11-22

³ <http://exporthelp.europa.eu/thdapp/comext/ComextServlet?languageId=EN>

⁴ http://ec.europa.eu/taxation_customs/dds/tarhome_en.htm

⁵ http://www.efsa.europa.eu/EFSA/ScientificPanels/efsa_locale-1178620753812_DATEX.htm

⁶ In terms of metric tonnage. These trade figures may be different if assessed using different criteria e.g. value of these products in Euros.

- (a) The provision(s) for use,
- (b) Dosing type(s)/method(s),
- (c) Withdrawal period(s), and
- (d) Maximum Residue Limit(s) (MRLs).

Over 180 contacts were made and replies, containing significantly different levels of detail, were received from 74 different organisations in 24 different Third Countries. Only in a few exceptional cases were full details provided, so a number of additional attempts were made to obtain missing data. In a number of cases the Third Country provided a link to official data on a public website. These websites were interrogated by Fera⁷ staff to obtain useful project data. A large amount of the supplied information also contained details on veterinary medicines that are currently authorised in the EU. These data were filtered against an online database containing all EU MRL data (www.fc24.eu) to identify those Third country veterinary medicines which are not authorised for use within the EU.

In addition to the direct contacts made to Third countries a series of electronic searches of databases of material available publicly, including scientific literature, national reports and national surveys, EU/National authorities' sources, federations of industries, single industries, journal/book archives, and web pages of governmental bodies, international organisations, and competent authorities were also made. These searches have provided useful MRL information for a number of Third countries, but in these cases it is difficult to confirm whether this information is accurate and up-to-date.

A final aim of this project was to obtain details of sales volumes of active substances of veterinary medicinal products in each of the Third countries. Unfortunately, most countries do not publish, or even collate, this information so this data set is far from complete and it is most unlikely that this commercially sensitive information would ever be collated by official organisations and then provided to the EFSA by Third countries.

Finally, it should be noted that the situation regarding the authorisation and use of veterinary medicines is fluid and subject to change at short notice. To help address this issue a bespoke web-based database was developed for this project (www.vetdrugscan.eu). This system has been used to track communication with Third Countries and to store both the trade statistics and the raw/processed veterinary medicine data in a user-friendly format. This database will serve two purposes. Firstly, it will provide EFSA with a fully searchable record of the available data and secondly the system will be available for tracking future changes in (i) the trade of animal products and (ii) the use of veterinary medicines in Third countries.

Key words: Veterinary medicines, residues, Maximum Residue Limits, Third countries

⁷ Fera, the UK Food and Environment Research Agency, see <http://www.defra.gov.uk/fera>

TABLE OF CONTENTS

Abstract.....	1
Summary.....	2
Table of contents.....	4
BACKGROUND TO PROJECT.....	5
1. Aims and approach.....	6
PROJECT RESULTS.....	8
1. Detailed overview of import statistics.....	8
1.1 Sources of information.....	8
1.2 Inclusion/exclusion criteria used.....	16
1.3 Correlation with DATEX.....	16
1.4 Tabulated trade data.....	17
2. Overview of veterinary medicinal product usage in Third countries – ordered by Third country.....	32
2.1 Sources of information.....	32
2.2 Provisions for use, Dosing type, Withdrawal period, Sales volumes, MRLs.....	33
3. Discussion of results.....	48
4. Limitations of the findings.....	52
4.1 Uncertainties in the numerical data obtained.....	52
4.2 Gaps in data/knowledge and possible ways towards filling them.....	52
CONCLUSIONS AND RECOMMENDATIONS.....	53
CONCLUSIONS.....	53
RECOMMENDATIONS.....	53
APPENDICES.....	see separate documents @ www.vetdrugscan.eu

APPENDIX 1. Correlation between TARIC and DATEX codes

APPENDIX 2. Letter and proforma used for data collection.

APPENDIX 3. Detailed information on MRLs and veterinary medicine use (listed by Third country).

BACKGROUND TO PROJECT

The authorisation of veterinary medicinal products in the European Union is based on scientific assessments of the quality, safety and efficacy of the product as laid down in Regulation (EC) No 726/2004⁸. The scientific assessments are performed by the European Medicines Agency (EMA). In principle, consumer exposure to pharmacologically active substances intended to be used in veterinary medicinal products for food producing animals and residues thereof in foodstuffs of animal origin should be limited to maintain a high level of consumer health protection while not compromising availability of veterinary medicinal products within the European Community. The safety of consumers from consumption of potential residues of veterinary medicinal products via foodstuffs of animal origin is included in the assessment, and, when necessary, Maximum Residue Limits (MRLs) established for the relevant residues of animal products. Imported animal products have to comply with the European legislation.

During the life of this project the European Commission replaced the original “MRL” Regulation (EEC) 2377/90 with a new piece of Community legislation, Regulation (EC) No 470/2009⁹. Article 18 of 470/2009 states that, “*When it is deemed necessary in order to ensure the functioning of controls of food of animal origin imported or placed on the market in accordance with Regulation (EC) No 882/2004¹⁰, the Commission may establish **reference points for action** for residues from pharmacologically active substances which are not subject to a classification in accordance with Article 14(2) (a), (b) or (c)¹¹”. The **reference points for action** shall be reviewed regularly in the light of new scientific data relating to food safety, the outcome of the investigations and analytical tests...and technological progress.*”. Under Article 19 of the same Regulation, “*the reference points for action shall be based on the content of an analyte in a sample, which can be detected and confirmed by reference control laboratories*”. Article 19 also states that the European Commission shall, “*where appropriate, submit a request to EFSA for a risk assessment as to whether the reference points for action are adequate to protect human health. In those cases, EFSA shall ensure that the opinion is given to the Commission within 210 days of receipt of the request*”. This means EFSA might be asked by the European Commission to carry out risk assessments related to residues of veterinary medicinal products, which are currently not authorised for use in the European Community. Selecting the appropriate residues for the assessment is essential in order to facilitate EFSA’s work, while ensuring the highest standards and

⁸ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. OJ L 136, 30.4.2004, p. 1-33.

⁹ Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin was replaced during the life of this project by Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009, laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council. OJ L 152, 16.6.2009 p. 11-22

¹⁰ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. OJ L 191, 28.5.2004, p. 1 -.

¹¹ (a) a maximum residue limit; (b) a provisional maximum residue limit; (c) the absence of the need to establish a maximum residue limit.

efficiency. Therefore, this project was commissioned to gain knowledge on the veterinary medicinal products used in Third countries exporting animal products to the European Union. The compilation of such data was to provide information on (1) animal products including farmed fish and other seafood, which are imported in major metric quantities into the European Union; (2) identification of the respective Third countries exporting these products into the European Union; (3) veterinary medicinal products authorised for therapeutic and/or prophylactic use for the respective animal species in these Third countries. This list was to be limited to veterinary medicinal products which are not authorised for use in the European Union; and (4) established MRLs and provisions for use of these veterinary medicinal products, as identified under point 3 were to be obtained and collated (where available). Compounds for which Minimum Required Performance Limits (MRPLs) have been laid down in Annex II to Decision 2002/657/EC¹² (chloramphenicol, nitrofurans metabolites, medroxyprogesterone and malachite green) were to be excluded from the survey as the MRPL values are already employed as reference points for action.

Aims and approach

This project was divided into four tasks to provide:

An overview of import statistics for foodstuffs of animal origin into the EU.

Detailed statistics for each Third (non-EU) country exporting products to the EU, aggregated at an animal species level.

Detailed information on the pharmacologically active substances of veterinary medicinal products authorised for therapeutic and/or prophylactic use in the food-producing animals in each Third country (where available).

A list of the applicable Maximum Residue Limits (MRLs) for the respective pharmacologically active substances of veterinary medicinal products as identified under Task (iii).

A summary of the approach taken to achieve the above tasks is summarised in Figure 1. A more detailed description of the work conducted by task is reported in the “PROJECT RESULTS” section. All information obtained during this project is available to authorised users in a fully searchable format at www.vetdrugscan.eu.

¹² Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results. OJ L 221, 17.8.2002, p. 8-36.

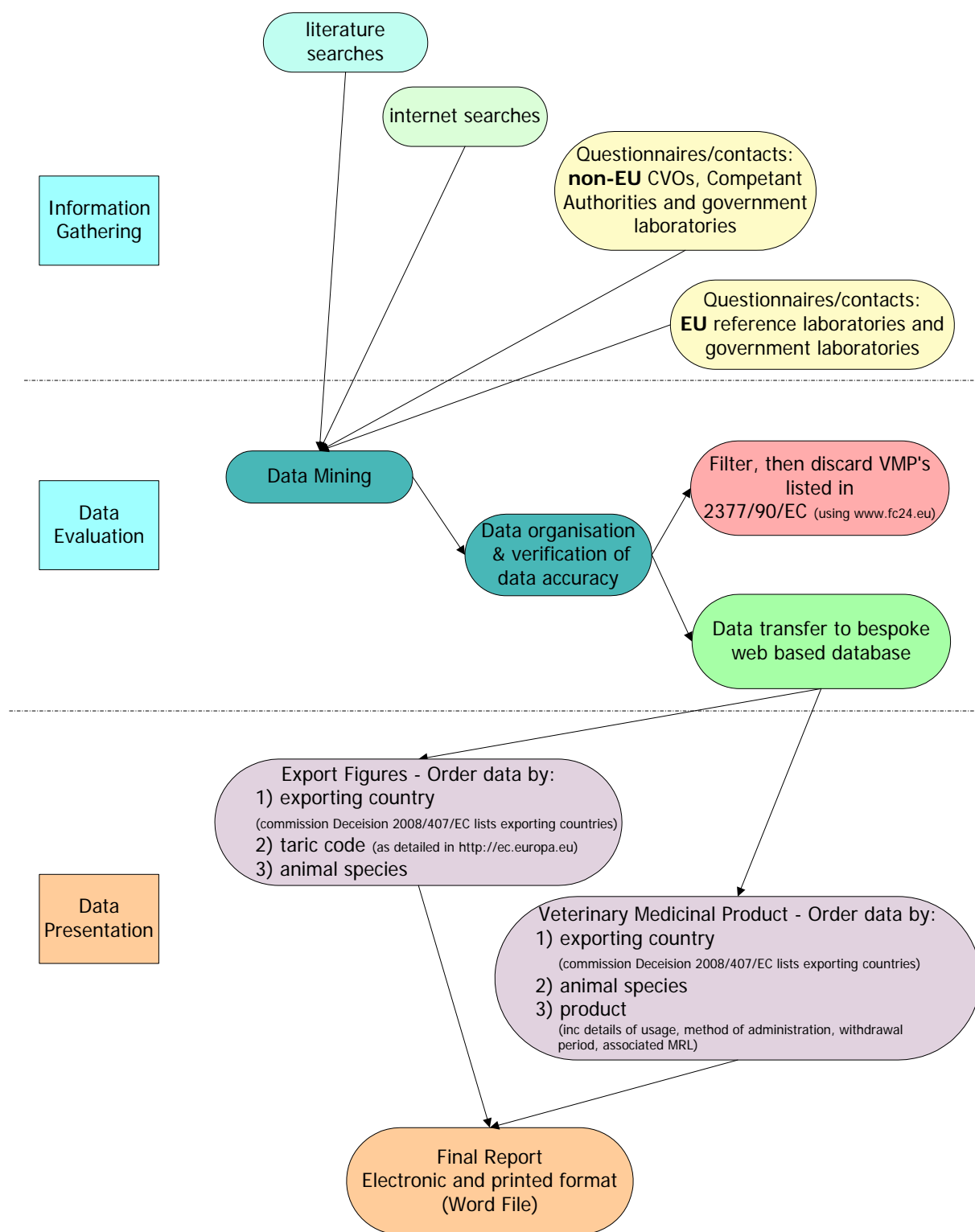


Figure 1. Summary of approach used for data collection, assessment/filtering and reporting.

PROJECT RESULTS.

1. Detailed overview of import statistics

1.1. Sources of information

A wide-ranging search of both literature and the Internet was conducted to obtain import statistics for animal products, including farmed fish and other seafood, into the EU from Third countries. The primary source for these data sets was identified as the EU Trade Helpdesk.¹³ Since this website covers trade in animal and non-animal products, it was important that only data from “*foodstuffs of animal origin from food-producing animals including farmed fish and shellfish*” was included in the search. To achieve this aim a master list of countries which export food of animal origin to the EU was produced using:

Commission Decision 2008/772/EC¹⁴. This EU Decision lists by country, commodities that can be exported to the EU from Third countries, and is an amendment to Commission Decision 2004/432/EC on the approval of residue monitoring plans submitted by Third countries in accordance with Council Directive 96/23/EC.

The EU Trade Control and Expert System (TRACES)¹⁵.

Table 1 presents a master list of the 207 Third countries included in this project, of which 103 are listed on the TRACES system and 80 are included in Commission Decision 2004/432/EC (as amended) for one or more classification(s) of animal products. The original agreement at the outset of this project was for trade data between 2003 and 2007 to be presented. However during the course of the project the actual date range was expanded to between 2002 and 2008. All of these data are available, by year, at the project website (www.vetdrugscan.eu).

Table 1. Products of animal origin:- List of countries for which Third country trade data with the EU are available. [A list of the available data relating to the use of veterinary medicines, by Third country, is also presented– see Section 2, below for a more detailed description].

¹³ <http://exporthelp.europa.eu>.

¹⁴ Commission Decision of 1 October 2008 amending Decision 2004/432/EC on the approval of residue monitoring plans submitted by third countries in accordance with Council Directive 96/23/EC. OJ L 263, 2.10.2008, p. 20-25

¹⁵ https://sanco.ec.europa.eu/traces/output/listsPerCountry_en.htm#.

Survey on use of veterinary medicinal products in third countries

No.	Country (for which searchable trade data between 2002 and 2008 are available on www.vetdrugsca.eu)	Country listed on EU "TRACES" system	Country listed in Commission Decision 2004/432/EC (as amended up until 01/10/2008)	Species for which residue monitoring plans have been submitted and approved under Commission Decision 2004/432/EC													MRL data available	List of authorised veterinary medicines available	Trade volumes of authorised veterinary medicines available	Sources of MRL /VMP information
				Bovine	Ovine / Caprine	Swine	Equine	Poultry	Aquaculture	Milk	Eggs	Rabbit	Wild Game	Farmed Game	Honey					
1	Afghanistan																			
2	Albania	x	x		x					x			x							
3	Algeria	x																		
4	American Samoa																			
5	Andorra		x	x	x		x													
6	Angola																			
7	Anguilla																			
8	Antarctica																			
9	Antigua and Barbuda	x																x	Official	
10	Argentina	x	x	x	x		x	x	x	x	x	x	x	x	x	x	x	x	in progress	
11	Armenia	x																x	Official	
12	Aruba																			
13	Australia	x	x	x	x		x			x	x			x	x	x				
14	Azerbaijan																			
15	Bahamas	x																		
16	Bahrain	x																		
17	Bangladesh	x	x							x										
18	Barbados																			
19	Belarus	x	x				x			x	x	x								
20	Belize	x	x							x										
21	Benin																			
22	Bermuda																			
23	Bhutan																			
24	Bolivia																			
25	Bosnia and Herzegovina	x	x							x										
26	Botswana	x	x	x											x				in progress	
27	Bouvet Island																			
28	Brazil	x	x	x			x	x	x							x			in progress	
29	British Indian Ocean Territory																			
30	Brunei Darussalam																			
31	Burkina Faso																			
32	Burundi																			
33	Cambodia																			
34	Cameroon																			
35	Canada	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	MRL (Government website) / VMP (Official)	

Survey on use of veterinary medicinal products in third countries

No.	Country (for which searchable trade data between 2002 and 2008 are available on www.vetdrugs.eu)	Country listed on EU "TRACES" system	Country listed in Commission Decision 2004/432/EC (as amended up until 01/10/2008)												MRL data available	List of authorised veterinary medicines available	Trade volumes of authorised veterinary medicines available	Sources of MRL /VMP information	
				Bovine	Ovine / Caprine	Swine	Equine	Poultry	Aquaculture	Milk	Eggs	Rabbit	Wild Game	Farmed Game					Honey
36	Cape Verde	x																	
37	Cayman Islands																		
38	Central African Republic																		
39	Ceuta																		
40	Chad																		
41	Chile	x	x	x	x	x		x	x	x			x		x				
42	China, People's Republic of	x	x					x	x			x	x		x	x			No.235 Announcement of Agricultural Ministry of PRC (as translated)
43	Christmas Island																		
44	Cocos Islands, or Keeling																		
45	Colombia	x	x							x							Use CODEX		
46	Comoros																		
47	Congo																		
48	Congo, Democratic Republic of																		
49	Cook Islands																		
50	Costa Rica	x	x							x									
51	Côte d'Ivoire	x																	
52	Croatia	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		Government website (data still to be translated)
53	Cuba	x	x							x						x			
54	Djibouti																		
55	Dominica																		
56	Dominican Republic																		
57	East Timor																		
58	Ecuador	x	x							x									
59	Egypt	x															Use CODEX		
60	El Salvador	x	x													x			
61	Equatorial Guinea																		
62	Eritrea																		
63	Ethiopia		x													x			
64	Falkland Islands	x	x	x	x														
65	Faroe Islands	x	x							x									
66	Fiji																		

Survey on use of veterinary medicinal products in third countries

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				Bovine	Ovine / Caprine	Swine	Equine	Poultry	Aquaculture	Milk	Eggs	Rabbit	Wild Game	Farmed Game					Honey	
67	French Polynesia	x																		
68	French Southern Territories																			
69	Gabon	x																		
70	Gambia	x	x							x										
71	Georgia																			
72	Ghana	x																		
73	Gibraltar																			
74	Greenland	x	x			x							x	x						
75	Grenada	x																		
76	Guam																			
77	Guatemala	x	x							x						x	Use CODEX			
78	Guinea	x																		
79	Guinea-Bissau																			
80	Guyana	x																		
81	Haiti																			
82	Heard Island and McDonald Islands																			
83	Holy See																			
84	Honduras	x	x							x							Use CODEX			
85	Hong Kong	x	x							x										
86	Iceland	x	x	x	x	x	x			x	x				x		x	x	x	Official
87	India	x	x							x	x	x					x			
88	Indonesia	x	x							x										
89	Iran, Islamic Republic of	x	x							x										
90	Iraq																			
91	Israel	x	x							x	x	x			x		x			
92	Jamaica	x	x							x							x			
93	Japan	x	x							x							x	x	x	Government/ Official website
94	Jordan																			
95	Kazakhstan	x																		
96	Kenya	x																		
97	Kiribati																			
98	Korea, Democratic People's Republic of																			
99	Korea, Republic of	x	x							x							x			
100	Kosovo																			
101	Kuwait																			

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				Bovine	Ovine / Caprine	Swine	Equine	Poultry	Aquaculture	Milk	Eggs	Rabbit	Wild Game	Farmed Game	Honey					
102	Kyrgyzstan		x														x			
103	Lao People's Democratic Republic																			
104	Lebanon	x																		
105	Lesotho																			
106	Liberia																			
107	Libyan Arab Jamahiriya																			
108	Liechtenstein																			
109	Macao																			
110	Macedonia	x	x	x	x		x				x									
111	Madagascar	x	x							x										
112	Malawi																			
113	Malaysia	x	x					x		x										
114	Maldives	x																		
115	Mali																			
116	Marshall Islands																			
117	Mauritania	x																		
118	Mauritius	x	x					x		x										
119	Mayotte	x	x							x										
120	Melilla																			
121	Mexico	x	x				x			x							x			
122	Mongolia	x																		
123	Montenegro	x	x	x	x	x	x										x	x		VMP (Official)
124	Montserrat																			
125	Morocco	x	x							x										
126	Mozambique	x	x							x										
127	Myanmar																			
128	Namibia	x	x	x	x									x	x					
129	Nauru																			
130	Nepal																			
131	Netherlands Antilles	x	x							x										
132	New Caledonia	x	x	x						x			x	x	x					
133	New Zealand	x	x	x	x		x			x	x		x	x	x	x	x	x		Government website
134	Nicaragua	x	x							x							x			
135	Niger																			
136	Nigeria	x																		
137	Niue																			
138	Norfolk Island																			

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				Bovine	Ovine / Caprine	Swine	Equine	Poultry	Aquaculture	Milk	Eggs	Rabbit	Wild Game	Farmed Game	Honey					
139	Northern Mariana Islands																			
140	Norway																			
141	Oman	x																		
142	Pakistan	x																		
143	Palau																			
144	Palestinian Territory Occupied																			
145	Panama	x	x							x										
146	Papua New Guinea	x																		
147	Paraguay	x	x	x													x			
148	Peru	x	x						x	x										
149	Philippines	x	x							x								x		
150	Pitcairn		x														x			
151	Qatar																			
152	Russian Federation	x	x	x	x	x	x	x		x	x				x	x				
153	Rwanda																			
154	Saint Helena																			
155	Samoa																			
156	San Marino		x	x		x											x			
157	São Tomé and Príncipe																			
158	Saudi Arabia	x	x							x										
159	Senegal	x																		
160	Serbia	x	x	x	x	x	x	x	x	x	x	x	x				x			
161	Serbia and Montenegro																			
162	Seychelles	x	x							x										
163	Sierra Leone																			
164	Singapore	x	x	x	x	x			x	x										
165	Solomon Islands																			
166	Somalia																			
167	South Africa	x	x											x	x					
168	South Georgia and South Sandwich Islands																			
169	Sri Lanka	x	x							x								x	x (? - to follow)	Official
170	St Kitts and Nevis																			
171	St Lucia																			
172	St Pierre and Miquelon	x																		
173	St Vincent & Grenadines																			
174	Sudan																			

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				Bovine	Ovine / Caprine	Swine	Equine	Poultry	Aquaculture	Milk	Eggs	Rabbit	Wild Game	Farmed Game	Honey					
175	Suriname	x	x						x											
176	Swaziland	x	x	x																
177	Switzerland		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	Official	
178	Syrian Arab Republic	x																		
179	Taiwan	x	x						x							x	x	x	Official	
180	Tajikistan																			
181	Tanzania, United Republic of	x	x						x							x	in progress			
182	Thailand	x	x					x	x							x	x		website	
183	Togo																			
184	Tokelau																			
185	Tonga																			
186	Trinidad and Tobago																			
187	Tunisia	x	x					x	x				x				in progress			
188	Turkey	x	x					x	x	x						x				
189	Turkmenistan	x																		
190	Turks and Caicos Islands																			
191	Tuvalu																			
192	Uganda	x	x													x				
193	Ukraine	x	x					x	x	x						x				
194	United Arab Emirates	x	x						x											
195	United States	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		Government websites	
196	U. S. Minor Islands																			
197	Uruguay	x	x	x	x				x	x			x	x	x	x	x			
198	Uzbekistan	x																		
199	Vanuatu																			
200	Venezuela	x	x						x											
201	Vietnam	x	x						x								x			
202	Virgin Islands, British																			
203	Virgin Islands, USA																			
204	Wallis and Futuna																			
205	Yemen	x																		
206	Zambia		x													x				
207	Zimbabwe	x	x													x				
	TOTALS IN EACH CATEGORY	108	85	29	25	16	23	25	65	25	19	12	20	22	39					
Countries listed in bold are in the top 10 countries that export to the EU for one or more product types.																				

All of the trade information obtained from the 207 Third countries has been organised in www.vetdrugscan.eu in accordance with the European Union Custom Codes (“TARIC”) and by exporting country. For example, at the top level, the TARIC codes are as follows;

TARIC code	Description
<u>0201</u>	Meat of bovine animals, fresh or chilled
<u>0202</u>	Meat of bovine animals, frozen
<u>0203</u>	Meat of swine, fresh, chilled or frozen
<u>0204</u>	Meat of sheep or goats, fresh, chilled or frozen
<u>0205</u>	Meat of horses, asses, mules or hinnies, fresh, chilled or frozen
<u>0206</u>	Edible offal of bovine animals, swine, sheep, goats, horses, asses, mules or hinnies, fresh, chilled or frozen
<u>0207</u>	Meat and edible offal, of the poultry of heading 0105, fresh, chilled or frozen
<u>0208</u>	Other meat and edible meat offal, fresh, chilled or frozen
<u>0209</u>	Pig fat, free of lean meat, and poultry fat, not rendered or otherwise extracted, fresh, chilled, frozen, salted, in brine, dried or smoked
<u>0210</u>	Meat and edible meat offal, salted, in brine, dried or smoked ; edible flours and meals of meat or meat offal

These data were further sub-divided into the next layer of “sub-codes”, which are typically two or three in number. For example, in the case of “0201 Meat of bovine animals, fresh or chilled” there are three sub-codes of;

- 0201 10 - Carcasses and half-carcasses – fresh or chilled.
- 0201 20 - Other cuts with bone in – fresh or chilled.
- 0201 30 - Boneless – fresh or chilled.

A screenshot from the www.vetdrugscan.eu website is shown in Figure 2.



Home Page

You are here: [Taric Information](#)

Search Taric Information

Search criteria

Year: (select a year) ▾

Country: (select a country) ▾

Taric Code: 0201 Meat of bovine animals, fresh or chilled ▾

Meat of bovine animals, fresh or chilled

Taric Sub Code: (select a taric sub code) ▾

Datex: (select a matrix) ▾

Eliminate EU countries from output:

Search >

Admin Tools

- Add new user
- View users
- CVO Entry
- Embassy Entry
- Manage Links
- Country Drug
- Log Out »

Communications

- Overview
- Officers Contacted
- Officers Replied

Search

- Taric Information
- Data By Country
- Non-EU Drugs

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Matthew Sharman
Built by KM@FERA

Figure. 2. Summary of web-based approach used for data collection, assessment/filtering and reporting.

1.2 Inclusion/exclusion criteria used

As all of the trade information was obtained via the EU Trade Helpdesk it is assumed that the majority of data will be from official sources and therefore none of these data were excluded from the final datasets.

1.3 Correlation with DATEX.

At the request of EFSA an attempt was made to correlate the TARIC codes used for EU/Third country trade with the food classification system provided by the DATEX Unit. This request proved problematic as, in a number of cases, there is no direct match between the descriptions of a matrix in the two different systems. Nevertheless, it was possible to achieve a correlation for a number of the entries and a Table containing these links can be found in Appendix 1. The project website was subsequently redesigned to allow a search by either TARIC or DATEX matrix classification, where available (see Figure 2).

1.4 Tabulated trade data

Whilst all of the detailed data relating to the trade of products of animal origin from Third countries to EU can be accessed at www.vetdrugscan.eu, Tables 2 to 17 (below) provide summary information on the top 10 countries which have traded with the EU over the years 2002 to 2008. All of these import data are expressed as:

- (i) total tonnes, and
- (ii) % of total imports

and are ranked from 1 (highest volume) to 10 (lowest volume) of trade over the last seven-year period.

Table 2 contains information on all types of animal products listed in Chapters 02, 03 & 04 of the EU TARIC system. These summary data are then divided into the different sub-levels of food type classification (based on major species) in Tables 3 – 18. From these tables it can be seen that the trade can be quite different according to country of origin. For example, in the case of Norway, the main trade is in fish, whereas for Brazil the major exports are beef and poultry (fowl).

To help with the interpretation of the risks associated with the top 10 countries that export to the EU, the EU Rapid Alert System for Food and Feed (RASFF)¹⁶ RASFF system was searched using a web-based system¹⁷. Figures 3 – 13 present the results of these searches in terms of (a) the type and (b) the number of notifications per category for the period 2002 to 2008. Where residues of veterinary medicines have been detected, both the country of origin and the class of veterinary medicine involved in the RASFFs are summarised at the bottom of each figure. Where available, other RASFF data from countries which are not in the top 10 list of exporters to the EU are also show at the bottom of each figure.

Table 2. Top 10 exporters of all produce listed in Chapters 02, 03 & 04 of TARIC to the EU over the years 2002-2008 (tonnes and % of total)

<i>Rank</i>	<i>Country</i>	<i>Tonnes</i>	<i>% of total</i>
1	Norway	5,192,400	14.1
2	Brazil	3,743,787	10.2
3	New Zealand	2,807,793	7.6
4	Argentina	2,559,752	6.9
5	China ,People's Republic of	2,292,135	6.2
6	United States	2,272,883	6.2
7	Iceland	1,618,049	4.4
8	Russian Federation	981,604	2.7
9	Vietnam	937,321	2.5
10	India	878,699	2.4

¹⁶ http://ec.europa.eu/food/food/rapidalert/index_en.htm

¹⁷ www.fc24.eu

Table 3. Top 10 exporters of fresh or frozen meat of bovine animals (TARIC Codes 0201 & 0202) to the EU over the years 2002-2008 (tonnes and % of total).

Rank	Country	Tonnes	% of total
1	Brazil	1,189,386	57.8
2	Argentina	455,437	22.1
3	Uruguay	182,220	8.9
4	Namibia	60,764	3.0
5	Botswana	57,853	2.8
6	Australia	49,324	2.4
7	New Zealand	20,561	1.0
8	United States	9,039	0.4
9	Serbia (+/- Montenegro)	8,993	0.4
10	Chile	7,307	0.4

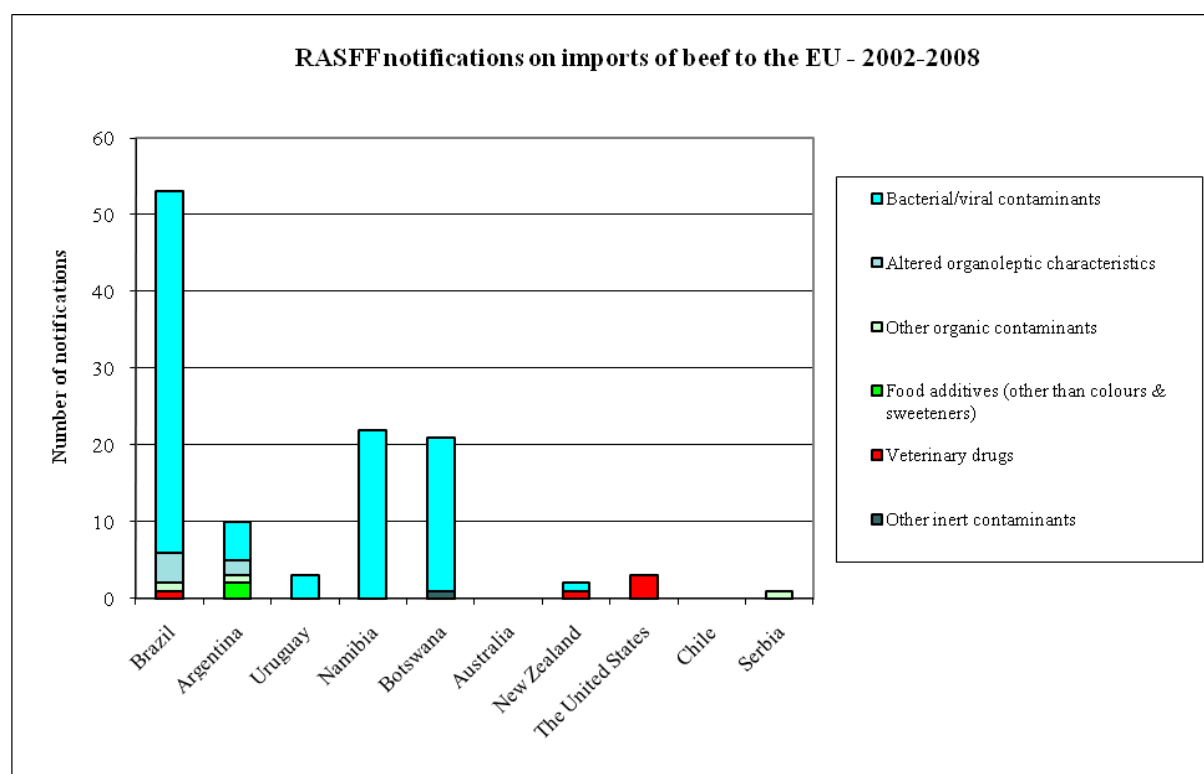


Figure 3. EU notifications for beef, 2002 -2008, (for the top 10 exporters to the EU).

Brazil, New Zealand – chloramphenicol
 United States – cloxacillin

Table 4. Top 10 exporters of fresh or frozen swine (TARIC Code 0203) to the EU over the years 2002-2008 (tonnes and % of total).

Rank	Country	Tonnes	% of total
1	United States	121,281	37.7
2	Canada	107,686	33.4
3	Chile	56,758	17.6
4	Brazil	13,453	4.2
5	Australia	13,422	4.2
6	Norway	3,671	1.1
7	Korea ,Republic of	1,408	0.4
8	Japan	1,100	0.3
9	Switzerland	741	0.2
10	Belarus	490	0.2

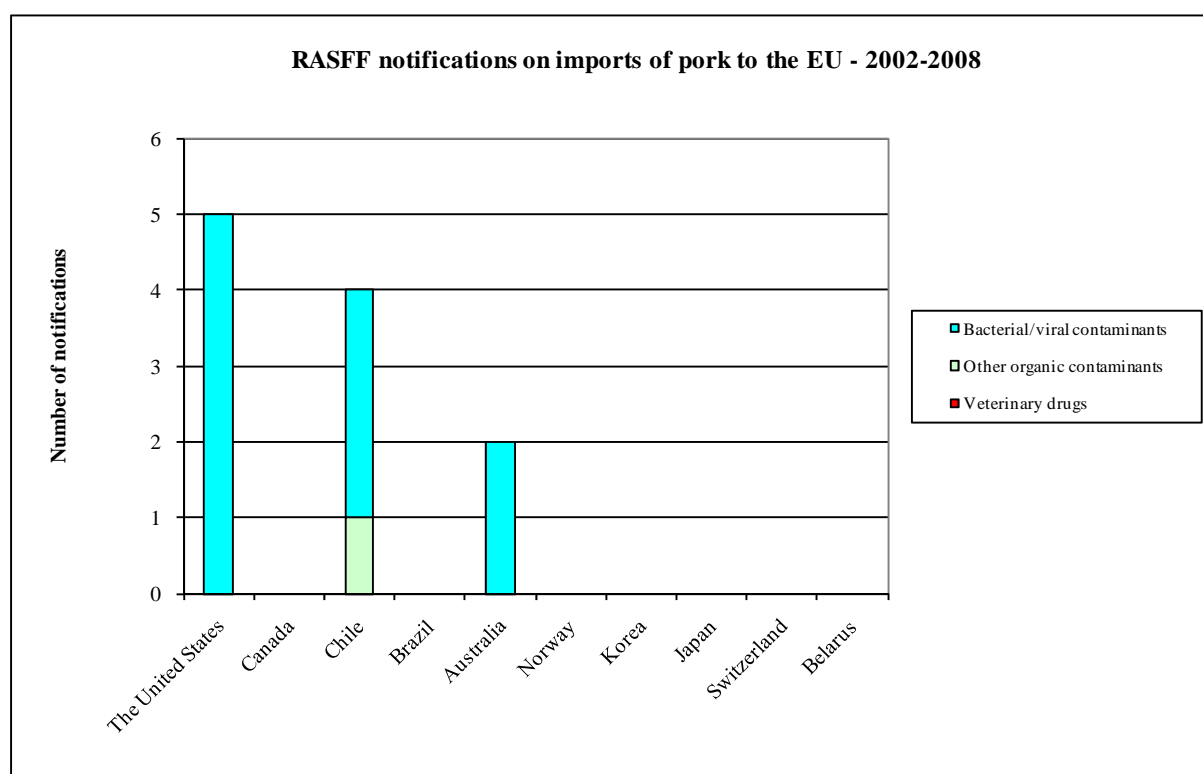


Figure 4. EU notifications for pork, 2002 -2008, (for the top 10 exporters to the EU).

Other countries not listed: China – nitrofurans (in pork casings)

Table 5. Top 10 exporters of fresh or frozen meat of sheep (TARIC Code 0204 excluding 020450) to the EU over the years 2002-2008 (tonnes and % of total).

Rank	Country	Tonnes	% of total
1	New Zealand	1,302,327	84.8
2	Australia	123,050	8.0
3	Argentina	33,823	2.2
4	Chile	25,460	1.7
5	Uruguay	24,788	1.6
6	Macedonia, Former Yugoslav Republic of	18,730	1.2
7	Iceland	4,960	0.3
8	Falkland Islands	1,509	0.1
9	Norway	520	0.0
10	Brazil	127	0.0

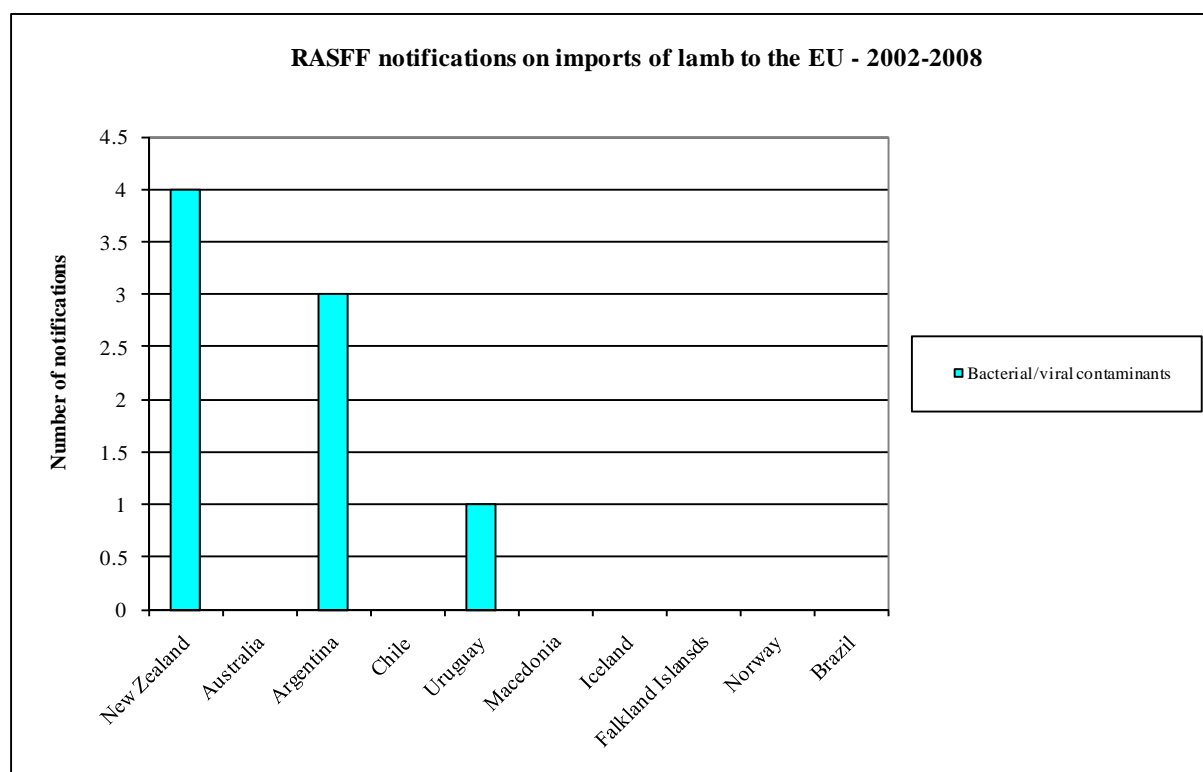


Figure 5. EU notifications for lamb, 2002 -2008, (for the top 10 exporters to the EU).

Other countries not listed: China – chloramphenicol (in sheep casings)

Table 6. The eight exporters of meat of goats (TARIC Code 020450) to the EU over the years 2002-2008 (tonnes and % of total).

<i>Rank</i>	<i>Country</i>	<i>Tonnes</i>	<i>% of total</i>
1	New Zealand	4,614	81.6
2	Australia	884	15.6
3	Chile	97	1.7
4	Argentina	49	0.9
5	Greenland	7	0.1
6	Macedonia	5	< 0.1
7	Croatia	< 1	< 0.1
8	Montserrat	< 1	< 0.1
9	Switzerland	< 1	< 0.1

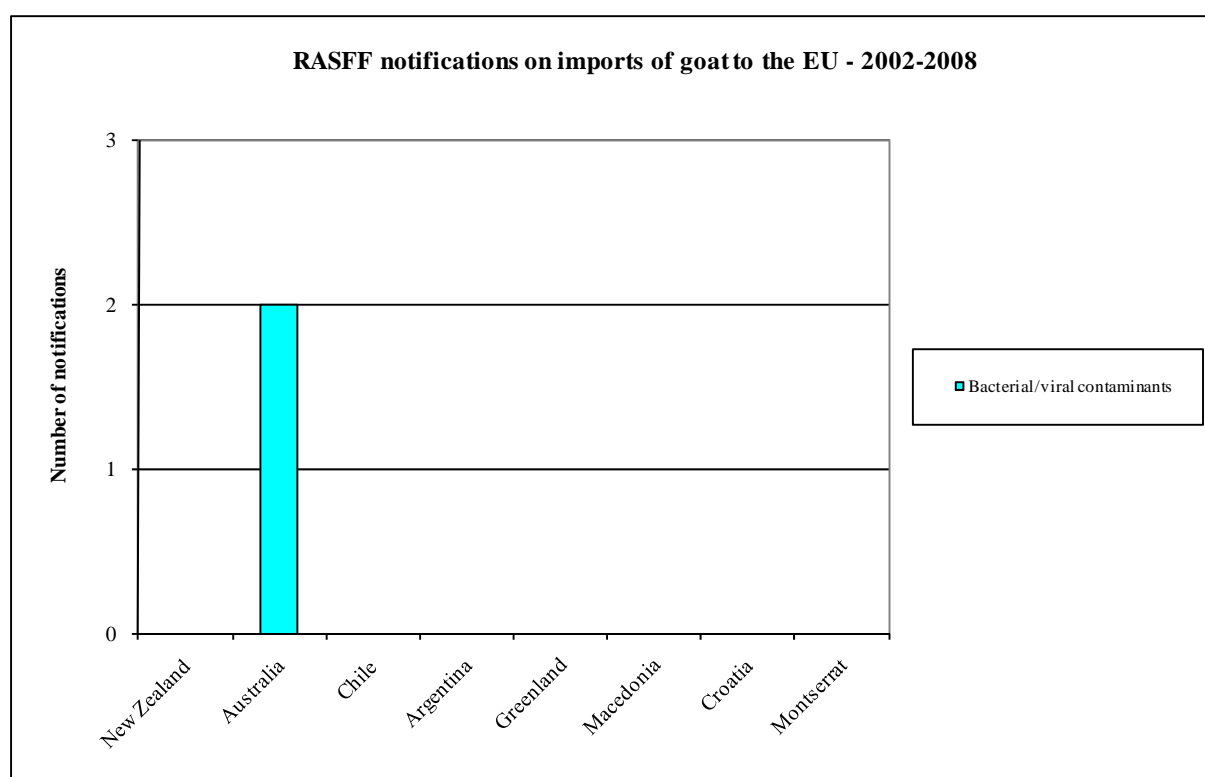


Figure 6. EU notifications for goat, 2002 -2008, (for the top 10 exporters to the EU).

Note: other than one report of pesticide residues in goat meat from Iran, no other contaminants were reported in this commodity.

Table 7. Top 10 exporters of meat and edible offal of the poultry (TARIC Code 0207) to the EU over the years 2002-2008 (tonnes and % of total).

Rank	Country	Tonnes	% of total
1	Brazil	1,369,801	68.5
2	United States	358,875	18.0
3	Thailand	85,111	4.3
4	Chile	65,075	3.3
5	Argentina	60,042	3.0
6	Canada	18,655	0.9
7	Israel	13,572	0.7
8	China ,People's Republic of	10,332	0.5
9	Turkey	3,054	0.2
10	Croatia	1,938	0.1

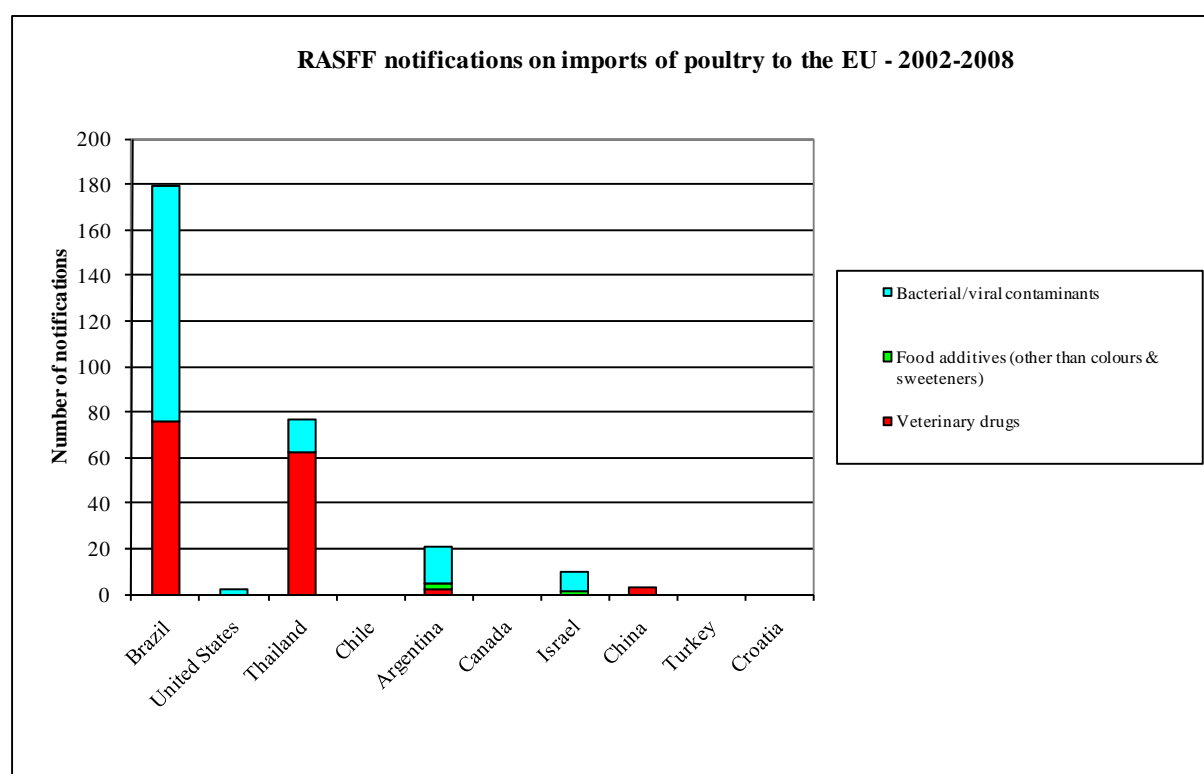


Figure 7. EU notifications for fowl, 2002 -2008, (for the top 10 exporters to the EU).

Brazil, Argentina, Thailand, China – nitrofurans.

Brazil – maduramycin, nicarbazin, and salinomycin.

Argentina – metronidazole.

Thailand – chloramphenicol.

Table 8. Top 10 exporters of fresh or frozen rabbit or hare (TARIC Code 020810) to the EU over the years 2002-2008 (tonnes and % of total).

Rank	Country	Tonnes	% of total
1	China ,People's Republic of	27,822	43.2
2	Argentina	24,895	38.7
3	Uruguay	1,967	3.1
4	Croatia	1,667	2.6
5	Chile	983	1.5
6	Canada	329	0.5
7	Namibia	31	< 0.1
8	Australia	19	< 0.1
9	South Africa	19	< 0.1
10	New Zealand	17	< 0.1

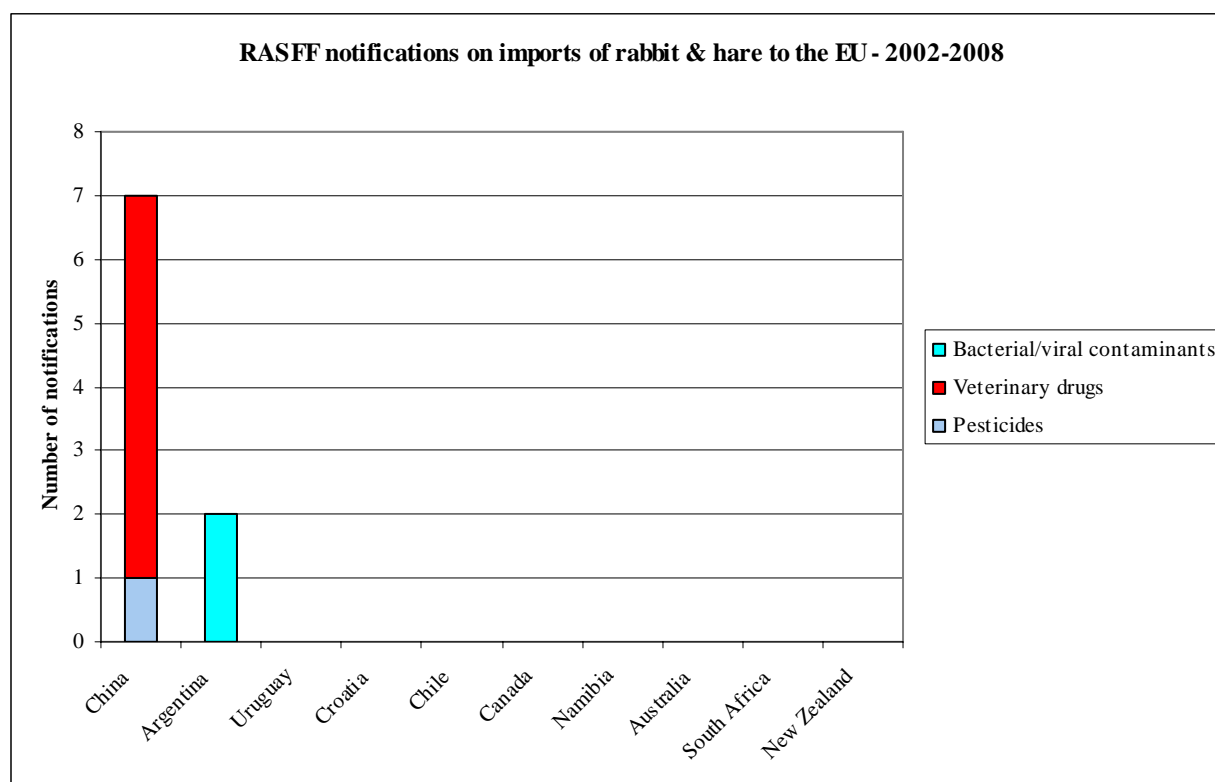


Figure 8. EU notifications for rabbit & hare, 2002 -2008, (for the top 10 exporters to the EU).

China – nitrofurans.

Table 9. Top 10 exporters of fish, fresh or chilled, excluding fish fillets and other fish meat (TARIC Code 0302) to the EU over the years 2002-2008 (tonnes and % of total).

Rank	Country	Tonnes	% of total
1	Norway	3,104,148	48.0
2	Faroe Islands	405,004	6.3
3	Iceland	350,719	5.4
4	Morocco	173,235	2.7
5	South Africa	121,176	1.9
6	Turkey	105,431	1.6
7	Chile	82,750	1.3
8	Canada	62,715	1.0
9	Croatia	47,879	0.7
10	Namibia	39,433	0.6

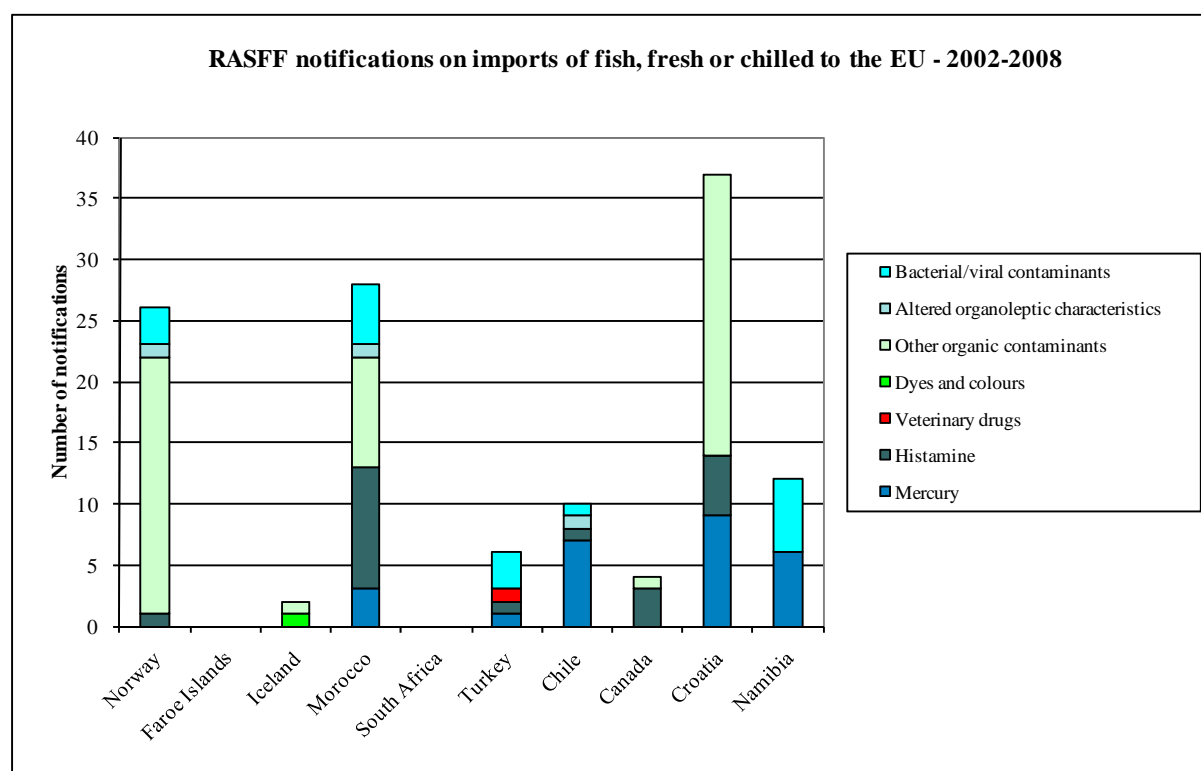


Figure 9. EU notifications for fresh or chilled fish, 2002 -2008, (for the top 10 exporters to the EU).

Turkey – enrofloxacin (actually from 2009, no records 2002-2008)

Other countries not listed:

Japan, Malaysia – (leuco)malachite green,

Jamaica – crystal violet.

Table 10. Top 10 exporters of fish, frozen, excluding fish fillets and other fish meat (TARIC Code 0303) to the EU over the years 2002-2008 (tonnes and % of total).

Rank	Country	Tonnes	% of total
1	Norway	582,376	12.1
2	United States	486,095	10.1
3	Russian Federation	447,194	9.3
4	Argentina	249,652	5.2
5	Seychelles	176,008	3.6
6	Namibia	169,618	3.5
7	Panama	163,908	3.4
8	South Africa	143,538	3.0
9	Morocco	139,937	2.9
10	China ,People's Republic of	138,069	2.9

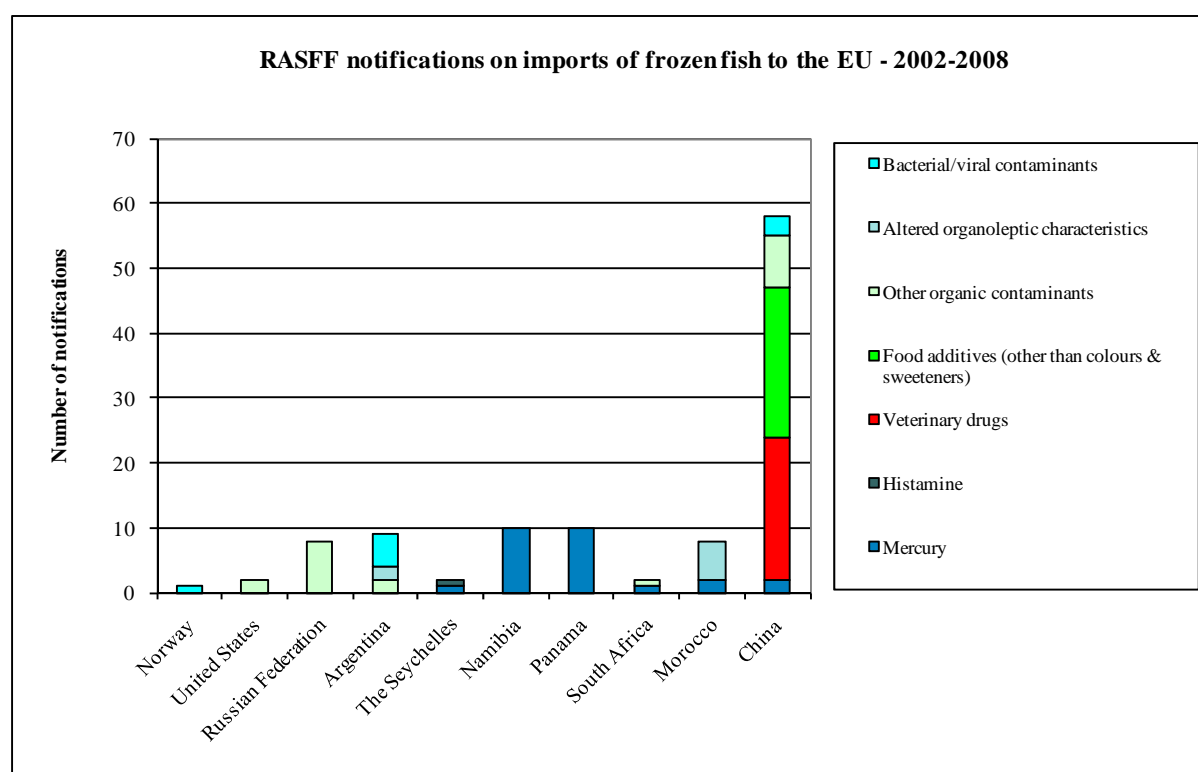


Figure 10. EU notifications for frozen fish, 2002 -2008, (for the top 10 exporters to the EU).

China – leucomalachite green

Other countries not listed:

Chile, Indonesia, Vietnam – (leuco)malachite green

Thailand - crystal violet

Taiwan, Peru – nitrofurans.

Myanmar – chloramphenicol.

Table 11. Top 10 exporters of crustaceans (TARIC Code 0306) to the EU over the years 2002-2008 (tonnes and % of total)

Rank	Country	Tonnes	% of total
1	Greenland	409,533	12.4
2	India	301,835	9.1
3	Ecuador	298,035	9.0
4	Argentina	237,867	7.2
5	Brazil	202,194	6.1
6	Canada	182,645	5.5
7	Bangladesh	166,813	5.0
8	China ,People's Republic of	163,419	4.9
9	Indonesia	136,090	4.1
10	Vietnam	81,434	2.5

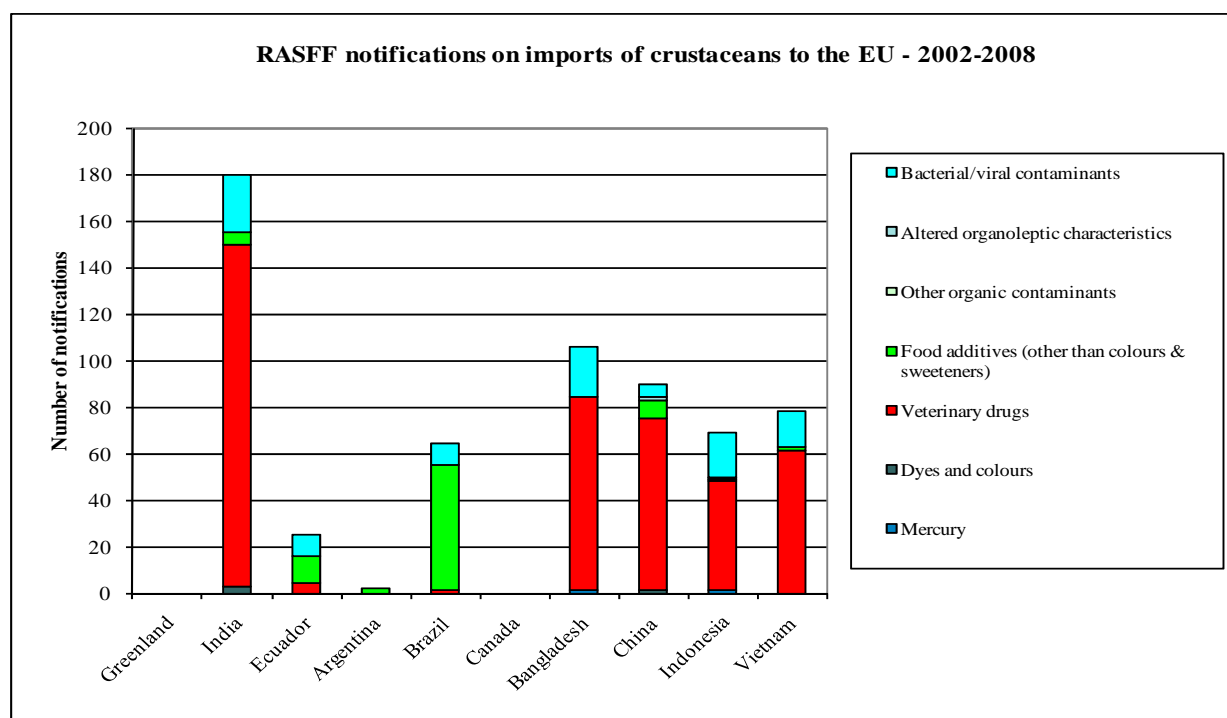


Figure 11. EU notifications for crustaceans, 2002 -2008, (for the top 10 exporters to the EU).

Ecuador, Brazil, India, China, Bangladesh, Indonesia, Vietnam – nitrofurans.

Other countries not listed:

Thailand, Madagascar, Malaysia, Turkey, United Arab Emirates, Venezuela – - nitrofurans.

Benin, Myanmar, Pakistan, The Philippines, Taiwan – chloramphenicol

The Philippines The Republic Of Korea – aminoglycosides

The Republic Of Korea – sulphonamides. Sri Lanka – tetracyclines.

Table 12. Top 10 exporters of fresh milk and cream (TARIC Code 0401) to the EU over the years 2002-2008 (tonnes and % of total).

<i>Rank</i>	<i>Country</i>	<i>Tonnes</i>	<i>% of total</i>
1	Macedonia	27,851	35.5
2	Switzerland	21,747	27.7
3	Croatia	16,661	21.2
4	Norway	5,789	7.4
5	Australia	4,691	6.0
6	China, People's Republic of	169	0.2
7	United States	89	0.1
8	Sierra Leone	88	0.1
9	Ukraine	65	0.1
10	Lebanon	58	0.1

No veterinary medicine residues in fresh milk or cream reported by the RASFF system between 2002 and 2008.

Table 13. Top 10 exporters of whey (TARIC Code 0404) to the EU over the years 2002-2008 (tonnes and % of total).

<i>Rank</i>	<i>Country</i>	<i>Tonnes</i>	<i>% of total</i>
1	Switzerland	335,638	90.0
2	Croatia	12,041	3.2
3	United States	6,283	1.7
4	Australia	5,450	1.5
5	New Zealand	3,314	0.9
6	Israel	3,006	0.8
7	Canada	2,779	0.7
8	Norway	827	0.2
9	Turkey	580	0.2
10	Indonesia	390	0.1

No veterinary medicine residues in whey reported by the RASFF system between 2002 and 2008.

Table 14. Top 10 exporters of butter (TARIC Code 040510) to the EU over the years 2002-2008 (tonnes and % of total)

<i>Rank</i>	<i>Country</i>	<i>Tonnes</i>	<i>% of total</i>
1	New Zealand	528,776	94.0
2	Australia	11,120	2.0
3	United States	7,601	1.4
4	Norway	4,342	0.8
5	Iceland	1,948	0.3
6	Argentina	1,726	0.3
7	Switzerland	1,615	0.3
8	Israel	1,062	0.2
9	Uruguay	742	0.1
10	Japan	718	0.1

No veterinary medicine residues in butter reported by the RASFF system between 2002 and 2008.

Table 15. Top 10 exporters of cheese & curd (TARIC Code 0406) to the EU over the years 2002-2008 (tonnes and % of total)

<i>Rank</i>	<i>Country</i>	<i>Tonnes</i>	<i>% of total</i>
1	Switzerland	294,072	40.1
2	New Zealand	230,449	31.4
3	Australia	122,827	16.7
4	Canada	29,151	4.0
5	Norway	22,417	3.1
6	United States	10,303	1.4
7	Ukraine	6,935	0.9
8	South Africa	6,342	0.9
9	Russian Federation	2,133	0.3
10	Croatia	2,033	0.3

No veterinary medicine residues in cheese reported by the RASFF system between 2002 and 2008.

Table 16. Top 10 exporters of eggs in shell (TARIC Code 0407) to the EU over the years 2002-2008 (tonnes and % of total)

<i>Rank</i>	<i>Country</i>	<i>Tonnes</i>	<i>% of total</i>
1	United States	28,596	42.0
2	Moldova ,Republic of	13,928	20.4
3	Canada	7,098	10.4
4	Albania	4,381	6.4
5	Turkey	3,532	5.2
6	Croatia	3,027	4.4
7	Brazil	1,700	2.5
8	Israel	1,312	1.9
9	Norway	1,007	1.5
10	China ,People's Republic of	728	1.1

No veterinary medicine residues eggs in shell reported by the RASFF system between 2002 and 2008.

Table 17. Top 10 exporters of dried or separated eggs (TARIC Code 0408) to the EU over the years 2002-2008 (tonnes and % of total)

Rank	Country	Tonnes	% of total
1	India	14,624.1	38.7
2	United States	13,145.4	34.8
3	Argentina	6,651.7	17.6
4	Canada	793.5	2.1
5	Israel	770.1	2.0
6	Brazil	497.8	1.3
7	China ,People's Republic of	326.0	0.9
8	Norway	286.9	0.8
9	Croatia	253.4	0.7
10	Mexico	108.1	0.3

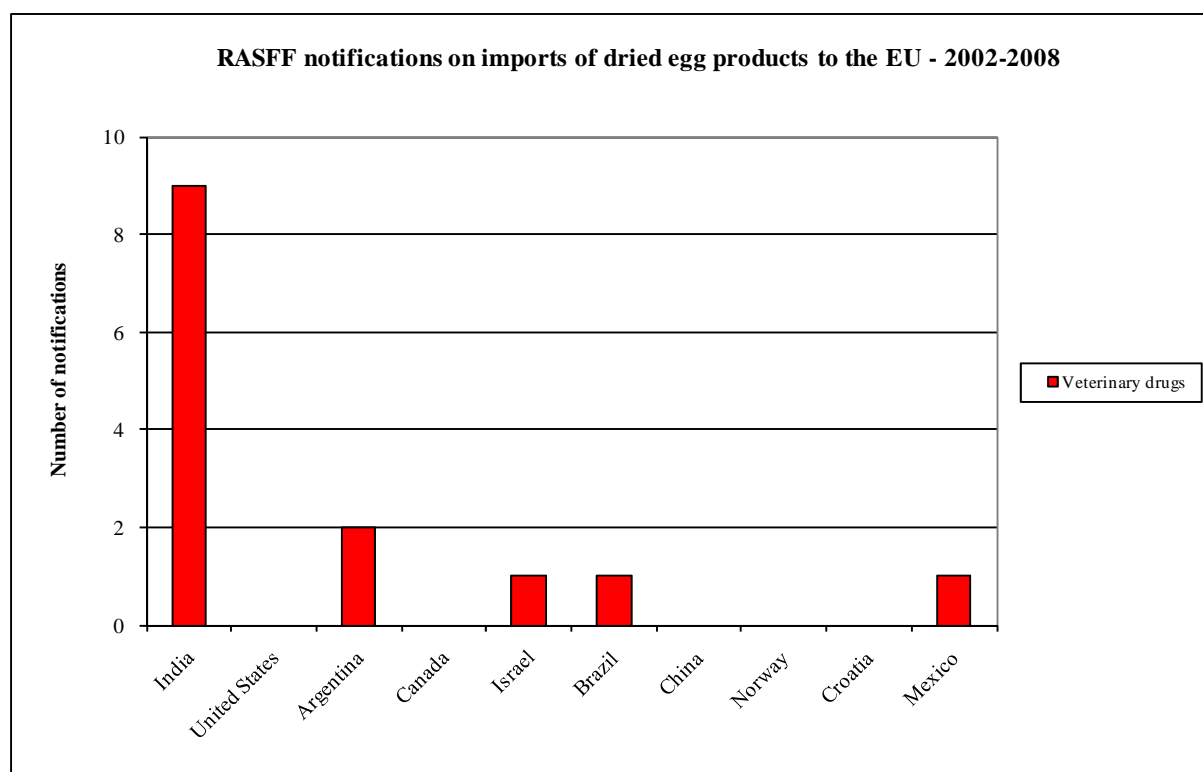


Figure 13. EU notifications for dried egg, 2002 -2008, (for the top 10 exporters to the EU).

India, Israel, Brazil, Mexico – nitrofurans.
 Argentina – unspecified antibiotics

Table 18. Top 10 exporters of honey (TARIC Code 0409) to the EU over the years 2002-2008 (tonnes and % of total)

Rank	Country	Tonnes	% of total
1	Argentina	395,149	42.9
2	Mexico	116,203	12.6
3	China ,People's Republic of	68,846	7.5
4	Uruguay	52,639	5.7
5	Brazil	51,261	5.6
6	Chile	41,363	4.5
7	India	34,065	3.7
8	Cuba	31,625	3.4
9	Turkey	30,831	3.3
10	Ukraine	19,853	2.2

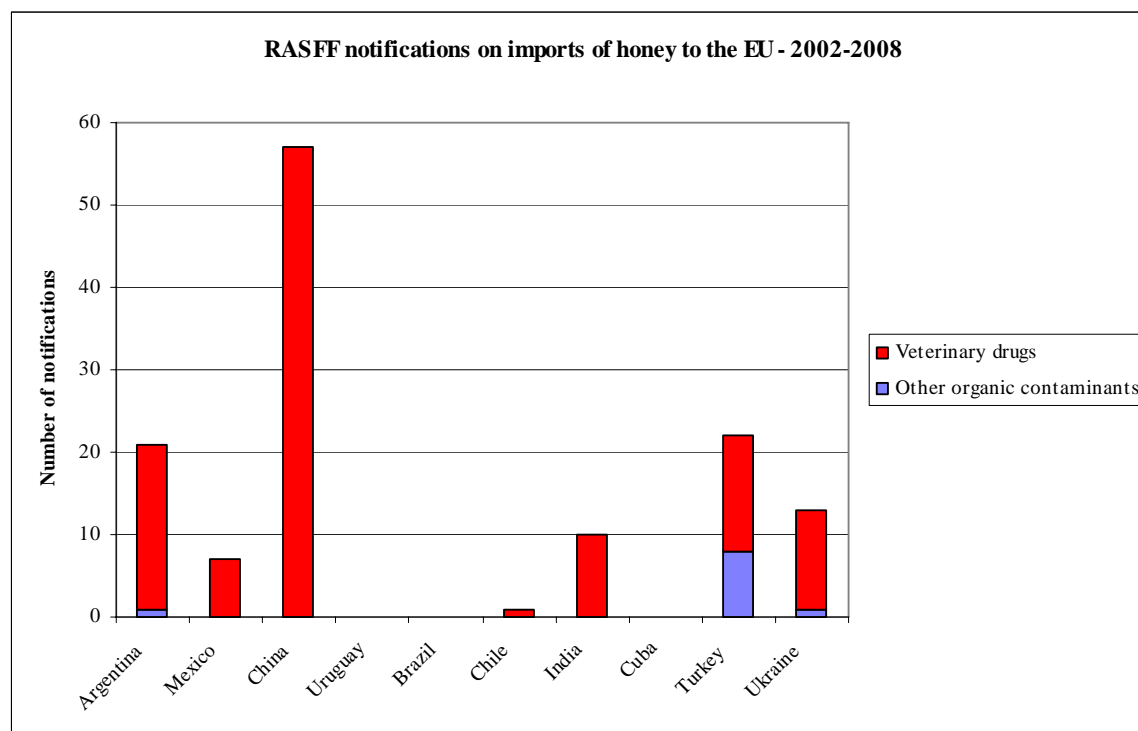


Figure 14. EU notifications for honey, 2002 -2008, (for the top 10 exporters to the EU).

Argentina – nitrofurans.

Chile, China, Mexico, Turkey, Ukraine– sulphonamides.

China, India –chloramphenicol

Other countries not listed:

Egypt, United States, Vietnam, - streptomycin. Moldova – chloramphenicol,

Israel – oxytetracycline. The Russian Federation, The United States – sulphonamides.

2. Overview of veterinary medicinal product usage in Third countries – ordered by Third country.

2.1 Sources of information

Information on the use of veterinary medical products being used in Third countries (that are not authorised for use within the EU) was obtained from four main sources:

- i) Direct contact with Chief Veterinary Officers (CVOs) in non-EU countries.
- ii) Direct contact with non-EU Government organisations.
- iii) Access to known web pages that already contain data by country /organisation.
- iv) « Other » targeted searches.

Further details on each of these sources are given below:

- Direct contact with Chief Veterinary Officers (CVOs) in Third countries.

The contact details for Chief Veterinary Officers in each Third Country were obtained from official sources. These details were added to www.vetdrugscan.eu, which was then used to track all further correspondence. In total 112 CVOs were contacted from countries ranging A (Albania) to Z (Zimbabwe). In some cases the CVO provided details of the other organisations that had the responsibility for licensing of veterinary medicines in their third countries and these contacts were followed up on a case-by-case basis. This resulted in contacts with over 180 official organisations, worldwide. In all cases a standard letter of request was accompanied by a *proforma*, in an attempt to standardise the data format. This letter and *proforma* are reproduced in Appendix 2.

- Direct contact with non-EU Government organisations.

Where the direct contact with CVO proved unsuccessful further attempts were made to obtain the information on veterinary medicine use in the Top 10 exporting countries by direct contact with other Government officials, Competent Authorities and other laboratories for which Fera already has established contacts worldwide.

- Access to known web pages that already contain data by country /organisation e.g.:

In a number of cases, Government websites containing information on the use of veterinary medicines were interrogated and the available data uploaded into www.vetdrugscan.eu. Links to these websites are all given in www.vetdrugscan.eu under the appropriate country and examples include:

United States:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=556>

Canada

<http://www.hc-sc.gc.ca/dhp-mps/vet/mrl-lmr/index-eng.php>

- « Other » targeted searches

All of the above information was supplemented by further searches of targeted Internet searches by Fera's dedicated Information Centre.

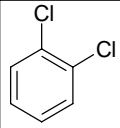
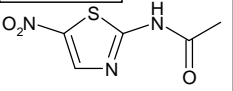
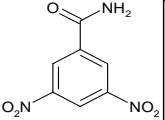
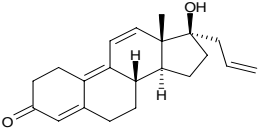
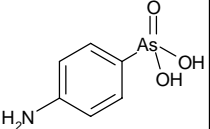
All information was screened using www.fc24.eu to assist in the elimination of any veterinary medicines that are listed in Annexes I, II or III of Regulation (EEC) 2377/90.

During this data transfer it was assumed that all Internet information on Government websites was up-to-date and factual. In some cases it was not possible to verify the information obtained from non-governmental sources. Where non-governmental sources have been used this is indicated in the following tables. The accuracy of this information is unknown and should therefore be treated with caution.

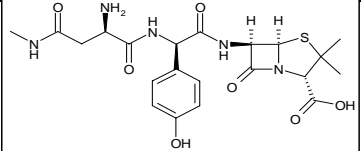
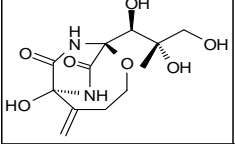
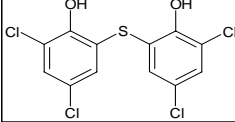
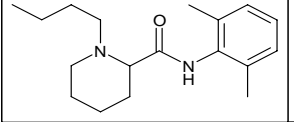
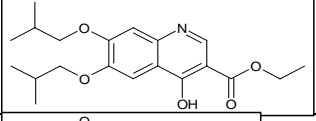
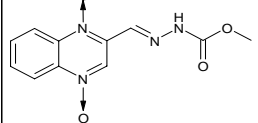
2.2 Provisions for use, Dosing method, Withdrawal period, Sales volumes, MRLs

Data obtained according to Section 2.1 resulted in over 100 veterinary medicines that are listed in Third country documentation, for which no equivalent medicine is authorised within the EU. It should be noted that this does not mean that all of these veterinary medicines are available for use as, in some cases, only MRL information has been obtained. A summary of these veterinary medicines (compound name, CAS No, references and, where available, chemical structure) is shown in Table 19. Further details, such as number of authorised products, by Third country, can be found in Appendix No.3. However, due the amount and complexity of the data obtained during this survey, all other information such as dosing method(s), withdrawal periods(s), and sales volumes (where available) and MRLs are only available at www.vetdrugscan.eu.

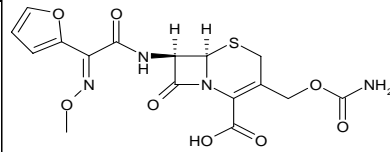
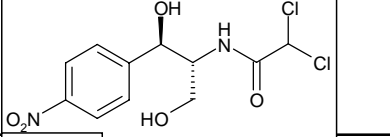

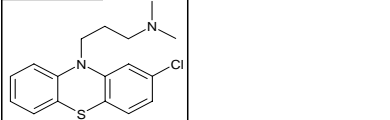
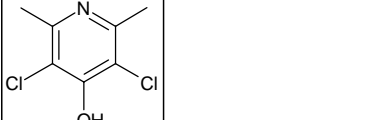
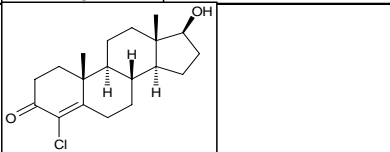
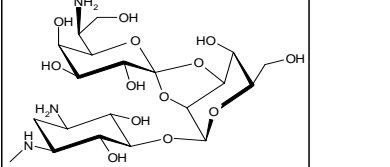
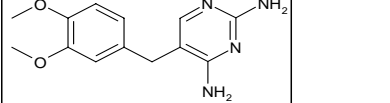
Table 19. Summary of veterinary medicines (compounds) listed in Third country documentation, listed in alphabetical order.

Compound	CAS No.	Comment	References	Structure
[monobis(trimethylammoniummethylene chloride)]-alkyltoluene	?		http://www.mhlw.go.jp/english/topics/mrls/dl/mrls6.pdf , www.ae17.com/product/product_13688.htm	
1,2-dichlorobenzene	95-50-1		www.chemindustry.com/apps/chemicals	
2-acetylamino-5-nitrothiazole	140-40-9	Also known as Aminitrozole - antiprotozoal (trichomonas), antihistomonad in turkeys		
3,5-dinitrobenzamide	121-81-3	Also known as Nitromide. Nitrobenzamide coccidiostat.	www.chemindustry.com/apps/chemicals	
Aklomide	3011-89-0	Nitrobenzamide coccidiostat - also known as 2-Chloro-4-nitrobenzamide		
Altrenogest	850-52-2	Progestagen	INN proposed list 46 (1981)	
Arsanilic acid	98-50-00/2045-00-3	Arsenic-containing antibacterial agent	(Martindale 33rd edition)	

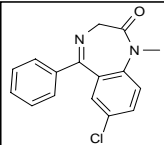
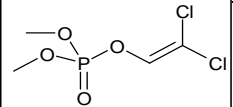
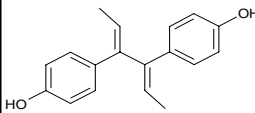
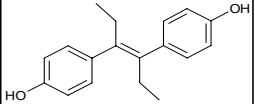
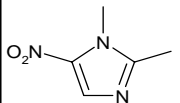
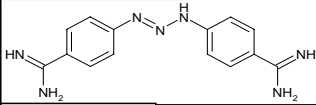
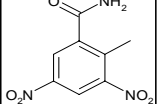
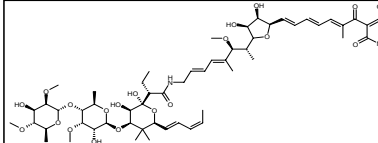
Survey on use of veterinary medicinal products in third countries

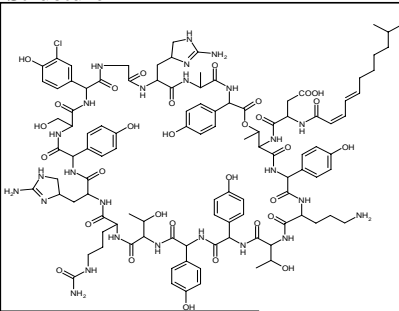
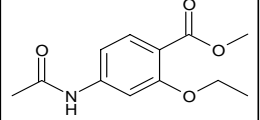
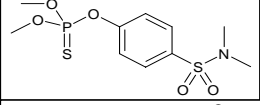
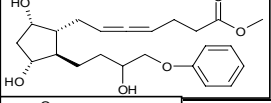
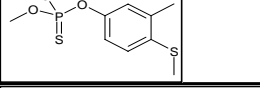
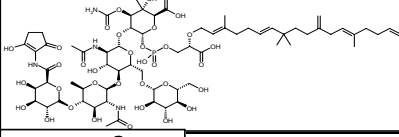
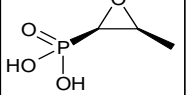
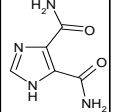
Compound	CAS No.	Comment	References	Structure
Aspoxicillin	63358-49-6	Amoxicillin derivative (almost certainly breaks down to amoxicillin)		
Bicozamycin	38129-37-2	A poorly absorbable antibiotic, in the treatment of acute diarrhea	INN proposed list 38 (1977)	
Bithionol	97-18-7	Phenolic anthelmintic, probably metabolises to sulfoxide and beyond.	A halogenated form of bisphenol used as an ingredient in germicidal soaps and as a medicine in the treatment of clonorchiasis. From www.drugs.com "An antiparasitic agent used for treatment of the human <i>lucumens, Bancroftii, malayi, and the Oriental</i>	
Bupivacaine	2180-92-9	Local anesthetic	www.chemindustry.com/apps/chemicals	
Buquinolate	5486-03-3	Quinolone coccidiostat related to decoquinolate and nequinolate.		
Carbadox	6804-07-5	Used in USA for growth promotion, Quinoxaline, banned in EU, monitored as QCA		

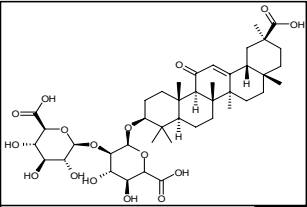
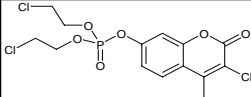
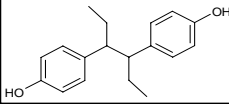
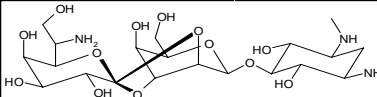
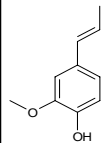
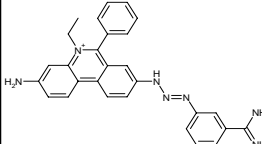
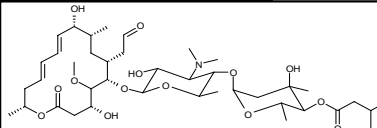
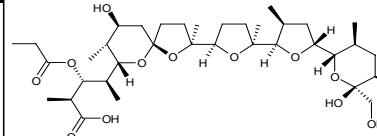
Survey on use of veterinary medicinal products in third countries

Compound	CAS No.	Comment	References	Structure
Cefuroxime	56238-63-2	2nd generation cephalosporin.		
Chloramphenicol	85666-84-8	Fenicol antibacterial	INN proposed list 01 (1953)	
Chlorobutanol	6001-64-5	Used as preservative in injectable solutions - 1,1,1-trichloro-2-methylpropan-2-ol		
Chlorpromazine	50-53-3	Promazine tranquilizer, Annex IV in EU. No MRPL or RPA		
Clopidol	68821-99-8	Pyridinol coccidiostat.		
Clostebol	855-19-6	Chlorotestosterone - androgen.	INN proposed list 22 (1969)	
Destomycin A	31282-04-9	Aminoglycoside antibiotic/anthelmintic		
Diaveridine	5355-16-8	Diaminopyrimidine coccidiostat/potentiator related to trimethoprim.	INN proposed list 18 (1967)	

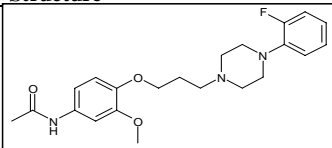
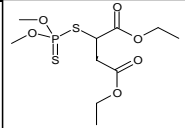
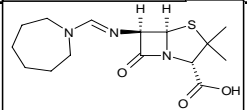
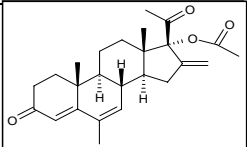
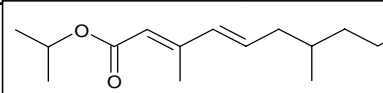
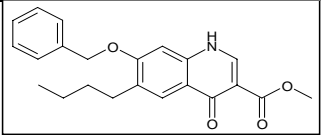
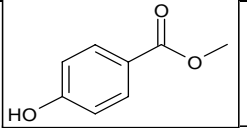
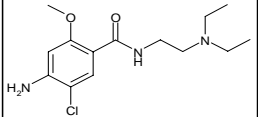
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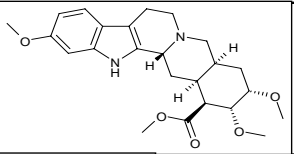
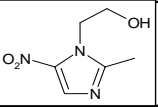
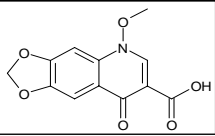
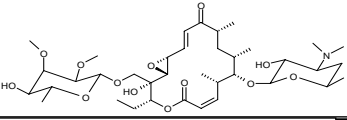
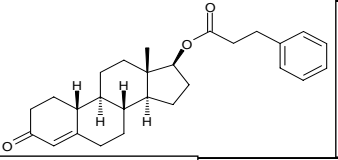
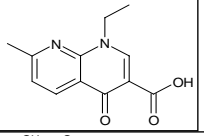
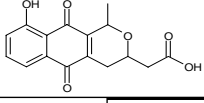
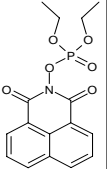
Compound	CAS No.	Comment	References	Structure
Diazepam	53320-84-6	Benzodiazepine tranquilizer/antidepressant		
Dichlorvos	95828-55-0	OP		
Dienestrol	84-17-3	Stilbene estrogen		
Diethylstilboestrol	8053-00-7	Stilbene estrogen	INN proposed list 04 (1956)	
Dimetridazole	551-92-8	Nitroimidazole antibiotic	INN proposed list 17 (1967)	
Diminazene	536-71-0	Antiprotozoal agent (Martindale 33rd edition)		
Dinitolmide (Zoalene)	148-01-6	Nitrobenzamide coccidiostat - related to aklomide		
Efrotomycin	56592-32-6	Antibiotic complex consisting of three major components, A1, A2, B		

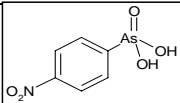
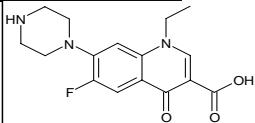
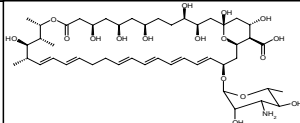
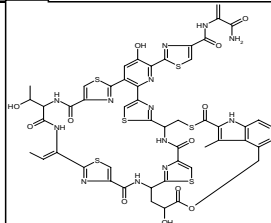
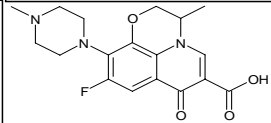
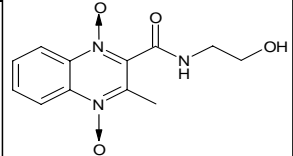
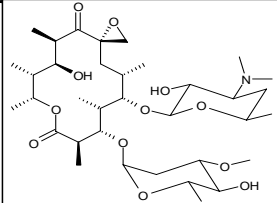
Compound	CAS No.	Comment	References	Structure
Enramaycin	11115-82-5	Possibly also known as enduracidin. Cyclic peptide antibiotic. Multicomponent complex (at least 3 components - A, B, SA). Enduracidin B shown		
Ethopabate	59-06-3	Coccidiostat		
Famphur	52-85-7	OP		
Fenprostalene	69381-94-8	Prostaglandin analogue		
Fenthion	55-38-9	OP		
Flavophospholipol	11015-37-5	Also known as bambermycin or moenomycin or flavomycin. Antribiotic complex consisting mainly of moenomycin A and C (C1-C4). Structure of Moenomycin A shown.	INN proposed list 21 (1969)	
Fosfomycin	78964-85-9	Phosphoric acid derivative. Antibiotic.		
Glycalpyramide	83-39-6	=glyclopamide (antidiabetic?) or glycarbylamide (coccidiostat) (structure shown)?	http://www.ehrenstorfer.com/eqweb/g.html	

Compound	CAS No. (to be added)	Comment	References	Structure
Glycyrrhizic acid	1405-86-3	Sweetener and anti-inflammatory derived from licorice root		
Haloxon	321-55-1	OP		
Hexoestrol	84-16-2/5635-50-7	Stilbene estrogen	INN proposed list 01 (1953)	
Hygromycin B	31282-04-9	Aminoglycoside antibiotic/anthelmintic		
Isoeugenol	97-54-1			
Isometamidium	34301-55-8	Antitrypanosomal		
Kitasamycin	39405-35-1	Macrolide antibiotic, also known as leucomycin A1. . Related to josamycin (leucomycin A3). Note Kitasamycin is sometimes used interchangeably with leucomycin		
Laidlomycin	56283-74-0	Ionophore coccidiostat structurally related to monensin. Included in ToF project.		

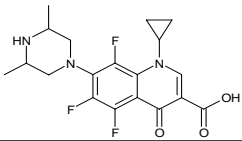
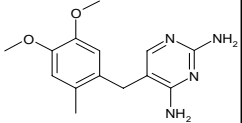
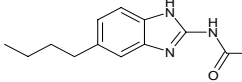
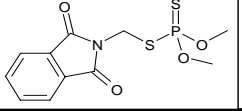
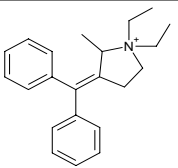
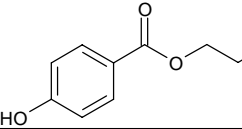
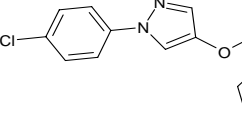
Survey on use of veterinary medicinal products in third countries

Compound	CAS No.	Comment	References	Structure
Mafoprazine	80428-29-1	Piperazine tranquilizer related to azaperol/azaperone	www.chemindustry.com/apps/chemicals	
Malathion	121-75-5	OP		
Mecillinum	32887-01-7	Possibly should be mecillinam? If so, also known as amdinocillin. Penicillin antibiotic.	INN proposed list 32 (1974)	
Melengestrol acetate	2919-66-6	Progestagen		
Methoprene	40596-69-8	Insect hormone analogue used as an insecticide	www.chemindustry.com/apps/chemicals	
Methylbenzoate	13997-19-8	Also known as nequinat. Quinolone coccidiostat related to decoquinat.		
Methylparaben	99-76-3	Preservative, antifungal, bacteriostatic	www.chemindustry.com/apps/chemicals	
Metoclopramide	364-62-5	Dopamine D2 antagonist, antiemetic		

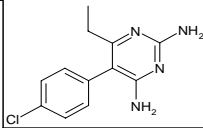
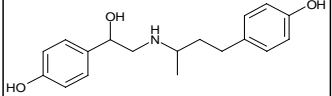
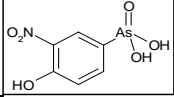
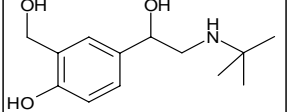
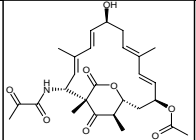
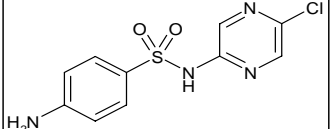
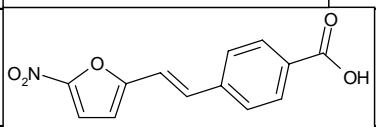
Compound	CAS No.	Comment	References	Structure
Metoserpate hydrochloride	1178-29-6	tranquilizer/sedative		
Metronidazole	99616-64-5	Nitroimidazole antibiotic	INN proposed list 11 (1961)	
Miloxacin	37065-29-5	Quinolone antibiacterial.	INN proposed list 40 (1978)	
Mirosamycin	73684-69-2	Macrolide antibiotic.	INN proposed list 58 (1987)	
Nadrolone phenylpropionate	62-90-8	Androgen. Nortestosterone ester.		
Nalidixic acid	389-08-2	Quinolone antibiotic		
Nanafrocin	52934-83-5	Also known as Nanaomycin A. Structurally related to Kanafungin (Nanaomycin D). Unknown usage, but kanafungin is an antifungal		
Naphthalphos	1491-41-4	OP		

Compound	CAS No. (to be added)	Comment	References	Structure
Nequinat	13997-19-18	See methyl benzoate		
Nitarson	98-72-6	Arsenic-containing antiprotozoal		
Norfloxacin	70458-96-7	Fluoroquinolone antibiotic		
Nystatin	93615-37-3 (mixture) (A1) 62997-67-5 (A3)	Polyene antifungal complex with 3 main components - A1, A2, A3.	www.chemindustry.com/apps/chemicals	A1 
Nosiheptide	56377-79-8	Cyclic peptide antibiotic		
Ofloxacin	82419-36-1	Fluoroquinolone antibiotic.	INN proposed list 49 (1983) and 64 (1990)	
Olaquinox	23696-28-8	Quinoxaline, banned in EU, monitored as mQCA		
Oleandomycin	3922-90-5	Macrolide antibiotic.	INN proposed list 06 (1958)	

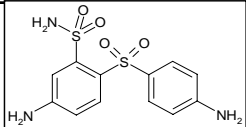
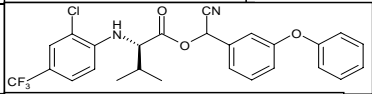
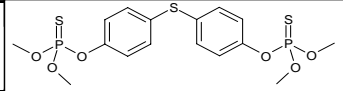
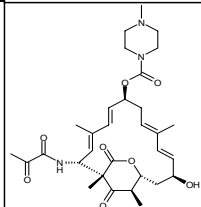
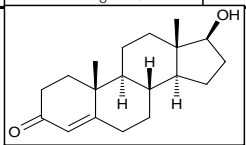
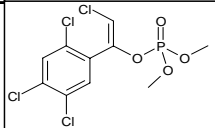
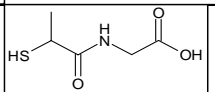
Survey on use of veterinary medicinal products in third countries

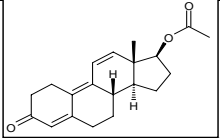
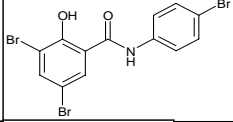
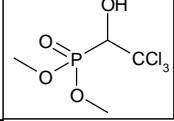
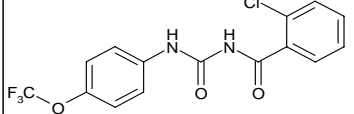
Compound	CAS No.	Comment	References	Structure
Orbifloxacin	113617-63-3	Fluoroquinolone antibiotic. On UK companion animal list.	INN proposed list 68 (1992)	
Ormetoprim	6981-18-6	Diaminopyrimidine antibacterial related to trimethoprim.	INN proposed list 21 (1967)	
Parbendazole	14255-87-9	Benzimidazole anthelmintic.	INN proposed list 19 (1968)	
Phosmet	732-11-6	Organophosphate insecticide	www.chemindustry.com/apps/chemicals	
Polymyxin B	1404-26-8	Cyclic peptide antibiotic related to (or possibly a component of) colistin (listed as polymixin E).		
Prifinium	10236-81-4	Anticholinergic. Also known as Pyrodifenium		
Propylparaben	94-13-3	Preservative	www.chemindustry.com/apps/chemicals	
Pyraclofos	77458-01-6	Organophosphate insecticide	www.chemindustry.com/apps/chemicals	

Survey on use of veterinary medicinal products in third countries

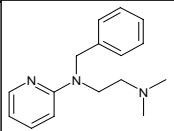
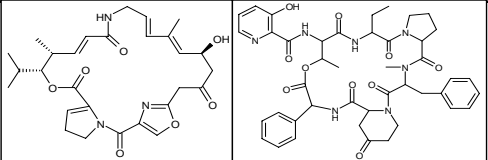
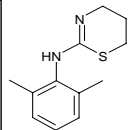
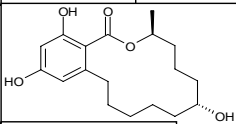
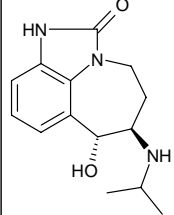
Compound	CAS No.	Comment	References	Structure
Pyrimethamine	58-14-0	Diaminopyrimidine antiprotozoal (antimalarial) related to trimethoprim.		
Ractopamine	97825-25-7	β -agonist		
Roxarsone	121-19-7	Arsenical coccidiostat		
Salbutamol	35763-26-9	β -agonist	INN proposed list 20 (1968)	
Sedecamycin	23477-98-7	Macrolide antibiotic.	INN proposed list 55 (1986)	
Sodium sulfachloropyrazine	102-65-8	Sulfonamide antibiotic (parent shown)		
Sodium nifurstyrenate	54992-23-3	Structure of parent acid given. Antibiotic used in fish		
Somatotropin (porcine)		Porcine growth hormone		

Survey on use of veterinary medicinal products in third countries

Compound	CAS No.	Comment	References	Structure
Various sulphonamides e.g. Sulfabromomethazine sodium	various	Sulfonamide		
Sulfamoyldapsone	17615-73-5	Combined dapsone - sulfanilide analogue		
Tau fluvalinate	102851-06-9	Insecticide		
Temephos	3383-96-8	Organothiophosphate insecticide	www.chemindustry.com/apps/chemicals	
Terdecamycin	113167-61-6	Macrolide antibiotic related to terdecamycin		
Testosterone	58-22-0	Androgen	INN proposed list 04 (1956)	
Tetrachlorvinphos	961-11-5	Organophosphate insecticide	www.chemindustry.com/apps/chemicals	
Tiopronin	1953-02-2	Amino acid derivative used in treatment of cystinuria		

Compound	CAS No.	Comment	References	Structure
Trenbolone acetate	10161-34-9	Androgen	www.chemindustry.com/apps/chemicals	
Tribromsalan	98518-05-9	Salicylanilide disinfectant/antiseptic		
Trichlorfon	52-68-6	OP. Also known as Metrifonate.		
Triflumuron	64628-44-0	Carbamate insecticide	www.chemindustry.com/apps/chemicals	

Survey on use of veterinary medicinal products in third countries

Compound	CAS No.	Comment	References	Structure
Tripelennamine	91-81-6	Antihistaminic		
Virginiamycin	11006-76-1	Peptide antibiotic complex consisting of M1 and S1 (structures shown)	INN proposed list 12 (1962) INN proposed list 17 (1967)	
Xylazine	7361-61-7	tranquilizer/sedative		
Zeranol	26538-44-3	Resorcylic acid lactone estrogen		
Zilpaterol	117827-79-9	β -agonist		

3. Discussion of results

Only 24 of the 112 Third countries that were contacted during the Spring / Summer of 2009 replied to the request for information on the use of veterinary medicines in their respective countries. Furthermore, although a standard *proforma* was prepared, only a few respondents returned information in the requested format. Consequently this survey was difficult to conduct, both in terms of (1) identifying the correct source of information and (2) the processing of the received data into a format that could be assessed against Regulation (EC) No 470/2009.

The majority of data in this report was obtained from official sources and the exact source is recorded on www.vetdrugscan.eu. In a number of cases the CVOs made available their “official data” by providing links to public websites of Government agencies/departments or other authorities with the responsibility for licensing veterinary medicines. In these cases a significant amount of extra work was required to obtain the necessary information. Whilst it has not been possible to validate the information taken from official websites, it is assumed that these sources must be reasonably up-to-date, and will therefore give a good indication as to the veterinary medicines used in these Third Countries.

This survey revealed that the types (classes) of veterinary medicines available in Third countries were quite diverse, when compared to Regulation (EC) No 470/2009, and included a number of antibiotics (e.g. kitasamycin, oleandomycin and orbifloxacin), coccidiostats (e.g. aklomide, buquinolate, nequinat) and a much larger number of veterinary medicines that can be used for growth promotion (e.g. carbadox, melengestrol acetate, ractopamine, trenbolone, zeranol, zilpaterol). One other interesting area is the sulphonamide class of antibiotics, where, although Regulation (EC) No 470/2009 contains an MRL definition of “all substances belonging to the sulfonamide group” a number of non-EU authorised sulphonomides are potentially available for use in Third countries.

Finally, whilst undertaking this project, it quickly became apparent that there are other issues relating to MRLs in Third countries that may require some consideration. These issues relate to a number of occasions whereby the same veterinary medicine is authorised in both the EU and a Third country but:

- (a) The MRL might not be the same for an identical analyte/matrix combination and,
- (b) Some Third countries may have additional MRLs in other combinations of species/products e.g. honey.

Therefore, to provide information on (b), an additional search facility has been developed for use within www.vetdrugscan.eu. EU Legislation is set at a range of levels for species, from single species like bovine, ovine or pheasant, through groups like all ruminants, poultry or fish, to all food producing species. Any combinations of these lower orders can also frequently occur so the EU database has to have a hierarchical relationship constructed to allow searching for any individual species to recognise larger encompassing groups. For

example, searches for MRLs set for bovine species must include those set for 'Bovine, ovine, caprine', 'Bovine, ovine, porcine, equidae', 'All ruminants', 'All food producing species except equidae', 'All mammalian food-producing species', 'All food-producing species' etc. A description of the hierarchy, with additional categories (in red) added in from other countries' MRL systems, is given in Figure 14.

In order to ensure that MRLs for drugs from Third countries, which are also approved within the EU, were not set for species/drug combinations not approved in the EU, a complex double linking system had to be constructed both at the species and tissue level. The tissue hierarchy used is given in Figure 15. This then enabled searches to be run for Third country MRLs against the EU MRL set. For example, Canada has MRLs set for diclazuril in chickens and turkeys and is approved as a premix with feed. However, although diclazuril has MRLs set for many species, chickens & turkeys for fattening are specifically excluded.

To allow this to happen, the database has to convert all records for multiple groups of species and tissues into their individual components in order to compare the two data sets.

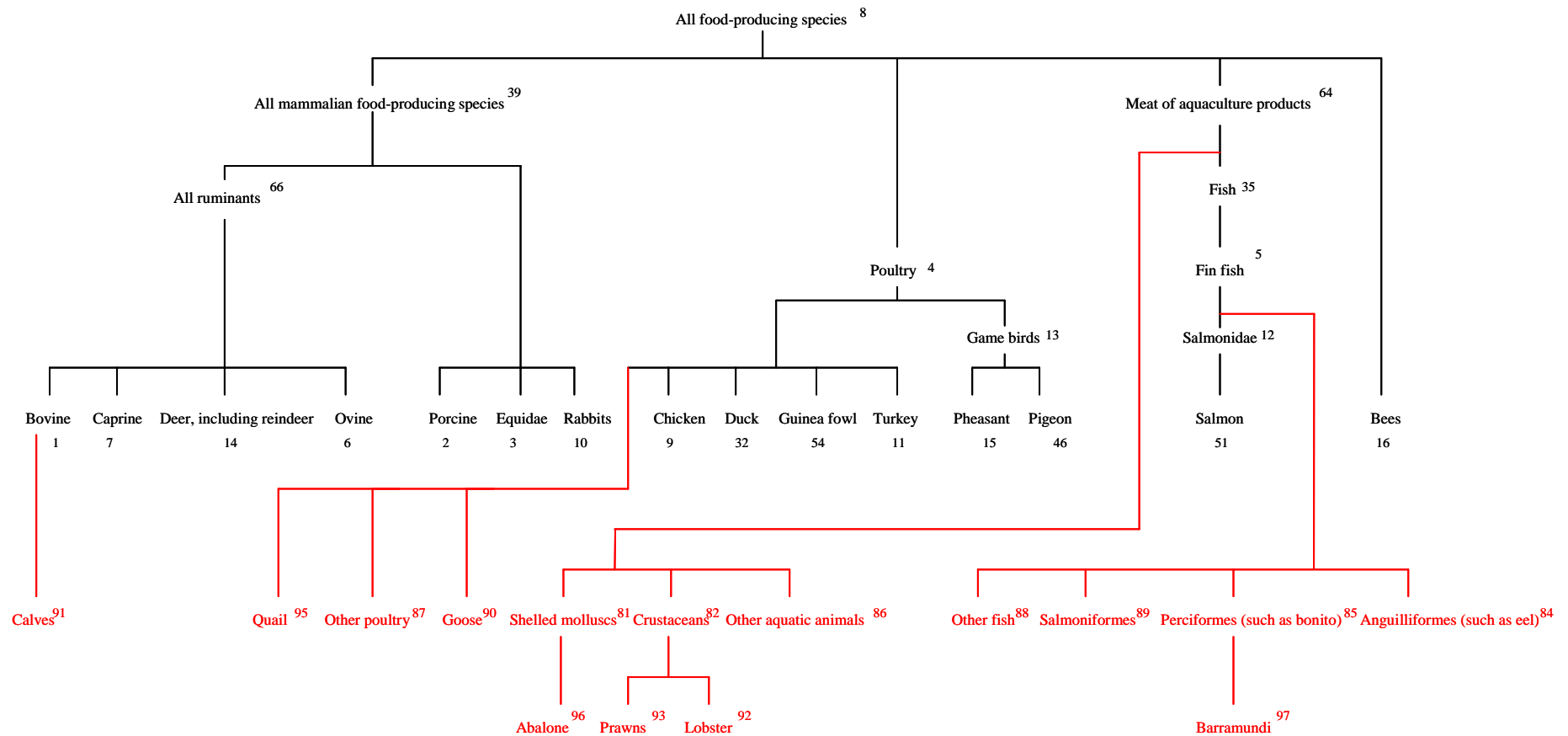


Figure 14. Hierarchy of species used in EU vet drug (black) and other country (red) classification

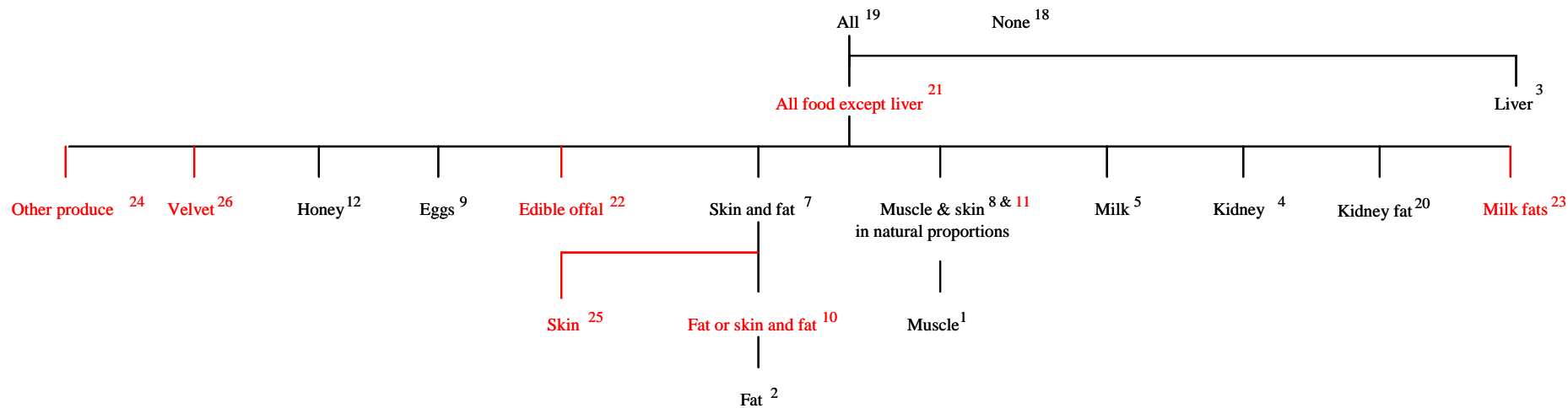


Figure 15. Hierarchy of tissues used in EU vet drug (black) and other country (red) classification

4. Limitations of the findings

4.1 Uncertainties in the numerical data obtained

All of trade data have been obtained from the EU trade figures and can therefore be assumed to be accurate. However, the absence of data at the sub-code level for certain sub-categories within TARIC code 0304 on the export helpdesk web site means this absence is similarly reflected in the vetdrugscan database. Ideally, when searching these trade data, the TARIC codes should be used. However, if the DATEX system is searched it must be recognised that, in many cases there is no direct match between the TARIC and DATEX codes and care should be taken when interpreting these data.

All information on veterinary medicine use (including MRL data) that was supplied by official channels can be regarded as factual. There is, however, one country (China) where the data was obtained from a public document via a commercial translation service. To date, it has not been possible for these MRL data to be validated. In addition, there are a number of cases whereby an MRL is known to exist within a Third country, but for which an authorised product has not been identified. Additional care should be taken in these cases, as the existence of an MRL does not necessarily confer the presence of an authorised veterinary medicine within that country.

4.2 Gaps in data/knowledge and possible ways towards filling them

The data obtained on trade between the Third countries and the EU can be regarded as complete and no further work is required. However, to keep this information up-to-date it would be relatively straightforward to update the data on an annual basis, once the base information has been published on the EU Trade system.

The situation regarding veterinary medicine use in Third countries is much less complete with data from 22 Third countries currently included within the web-based system. Nevertheless, the currently available MRL and authorisation data do include most of the top-10 Third countries (by volume/commodity) that trade with the EU. The most notable exceptions from this list are the Russian Federation and India. One of the severe limitations from the survey is the lack of sales volume information for each of the veterinary medicines. In most cases it appears that countries do not keep this commercially sensitive data and it is unlikely that any further efforts to fill these data gaps will be successful.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

This project has highlighted those countries which play a major role in exporting all the principal animal food commodities to the European Union. For many of these countries, suitable information on authorisation or MRLs has allowed recognition of which veterinary medicines may be used within those countries (and for which food producing species), and through real-time comparison with current MRLs as set within the EU, offers the instant identification of potential drugs and drug/species combinations not currently registered across the EU.

This project has created an on-line infrastructure which can be readily maintained and expanded as further information is sourced, while in the background it assesses this in real time against the EU MRL dataset which will continue to be maintained current after the end of this project under FP7 MoniQA funding.

RECOMMENDATIONS

By allowing recognition of drugs which may be used in particular Third countries of interest, the system should now be populated with information on actual registration and use data of relevant products for that country to confirm such use. It is therefore recommended that further funding is extended to continue this project into the future.

Some important exporting countries have not been forthcoming with information for the survey. The project should be continued to allow further time for contact by various means, further searching and collation of relevant data in order to fill these gaps. Direct contact with experts in these countries via other projects may well prove the best method for obtaining the required information.

This project has illustrated how sophisticated database systems, coupled with user-friendly web-based front ends, can provide instant access to information on incompatible veterinary medicine approvals between Third country exporters and the EU. Maintenance, expansion and periodic refreshing of the information into the future are recommended.

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Survey on use of veterinary medicinal products in third countries

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