The EU 'Hygiene Package': it's origins and implications for project countries and species

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In the aftermath of the BSE crisis and several other food scandals, the EU decided to have an action plan for a pro-active new food policy.

It has developed a “Farm to Fork” approach covering all sectors of the food and feed chain, with traceability as a basic concept.

Key elements in the new approach:

- the establishment of a framework regulation,

- the establishment of an independent body providing scientific advice to the legislators,

- the development of specific food and feed safety legislation including a major overhaul of the existing hygiene legislation

- the creation of a framework for harmonized food controls.

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In January 2002, the EU adopted the framework legislation in Regulation(EC) No.178/2002 laying down the general principles and requirements of EU food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

In April 2004, the EU adopted the three basic Acts forming the core of the so-called "Food Hygiene Package"

The ‘hygiene package’ is a body of EU law laying down hygiene rules for foodstuffs produced in the EU and non-EU countries exporting to the EU, and includes the following acts:

Regulation (EC) No. 852/2004 on the hygiene of foodstuffs

Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin in order to guarantee a high level of food safety and public health

Regulation (EC) No. 854/2004 putting in place a Community framework of official controls on products of animal origin intended for human consumption

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The ‘hygiene package’ is supplemented by other EU legislation on food hygiene

Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products

Imports of fishery products, including those from aquaculture

The EU is by far the world's biggest importer of fish, seafood and aquaculture products.

Import rules for these products are harmonised, meaning that the same rules apply to all EU Member States

For non-EU countries, the European Commission is the negotiating partner that defines import conditions and certification requirements. Also, for most countries with existing trade, the Commission negotiates on behalf of all 27 Member States.

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Imports of fishery products into the EU are subject to official certification based on recognition of the Competent Authority (CA) of the non-EU country by the European Commission.

Public authorities with the necessary legal powers and resources must ensure credible inspection and control throughout the production chain, which covers all relevant aspects of hygiene, public health and, in the case of aquaculture products, also animal health.

For all fishery products, countries of origin must be on a published list of eligible countries for the relevant product.

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Thus, countries wishing to export aquaculture products to the EU must first be approved by the European Commission.

The countries must have a Competent Authority responsible for official controls throughout the production chain.

The CA must be empowered, structured and resourced to implement effective inspection and guarantee credible public health and animal health attestations in the certificate to accompany fishery products destined for the EU.

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In the case of aquaculture products, a control plan for heavy metals, contaminants, residues of pesticides and veterinary medicines must be in place to verify compliance with EU requirements.

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Approval of a country is dependent on its compliance with the veterinary residue monitoring requirements outlined in Directive 96/23/EC.

The exporting country must submit a plan setting out the guarantees it can provide as regards the monitoring for veterinary residues and other substances listed in Annex 1 of Directive 96/23/EC.

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The residue monitoring programme must be submitted by the Competent Authority of the exporting country to the European Commission for initial approval and must be resubmitted annually for evaluation and renewal of approval.

The aim of the evaluation is to asses whether the exporting country's regulatory systems for the control of contaminants, veterinary residues, the authorisation of veterinary medicinal products, and the control plan provide guarantees which are at least equivalent to those provided by EU legislation.

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Approval is based on the guarantees received on paper but if a subsequent inspection in the exporting country by the EC Food and Veterinary Office (FVO) to assess the implementation of residues and veterinary medicines controls reveals that the paper guarantees cannot be relied upon, the status of the country could be revised.

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Key requirements of the guarantees are:

- a full description is given of the legislation governing the authorisation, distribution and use of veterinary medicines

- a centrally co-ordinated residue monitoring plan is in place

- the number of samples taken is in accordance with the sampling levels and frequencies laid down in Annex IV of Directive 96/22/EC

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COUNCIL DIRECTIVE 96/23/EC

of 29 April 1996

on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Parliament [2],

Having regard to the opinion of the Economic and Social Committee [3],

(1) Whereas by Directive 96/22/EC [4] the Council decided to maintain the prohibition on the use of certain substances having a hormonal or thyrostatic action, by extending it to beta-agonists having an certain number of residues of pharmacological substances and of environmental contaminants in farm animals and in the fresh meat obtained from such animals; whereas such monitoring should be extended to cover other animal species and all animal products for human consumption;

(5) Whereas 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 [7] laid down in its Annexes limits for certain veterinary medicinal products;

(6) Whereas the Community legislation on monitoring residues in meat lacks clarity, giving rise to varying interpretations in the different Member States;

ANNEX III

SAMPLING STRATEGY

1. The residue control plan is aimed at surveying and revealing the reasons for residue hazards in foods of animal origin on farms, slaughterhouses, dairies, fish processing plants, and egg collecting and packing stations.

   Official samples are to be taken in accordance with the relevant chapter of Annex IV.

   Wherever official samples are taken, sampling must be unforeseen, unexpected and effected at no fixed time and on no particular day of the week. The Member States must take all the precautions necessary to ensure that the element of surprise in the checks is constantly maintained.

2. For Group A substances, surveillance should be aimed at detecting the illegal administration of prohibited substances and the abusive administration of approved substances, respectively. The emphasis of such sampling must be concentrated according to the relevant chapter of Annex IV.

   The samples must be targeted taking account of the following minimum criteria: sex, age, species, fattening system, all available background information, and all evidence of misuse or abuse of substances of this group.

   The details of these criteria will be laid down in the Commission Decision provided for in Article 15 (1).

3. For Group B substances, surveillance should be aimed particularly at controlling the compliance with MRLs for residues of veterinary medicinal products fixed in Annexes I and III to Regulation (EEC) No 2377/90, and the maximum levels of pesticides fixed in Annex III to Directive 86/363/EEC, and monitoring the concentration of environmental contaminants.

   Unless random sampling can be justified by Member States when presenting their national plans to the Commission, all the samples shall be targeted according to criteria laid down in the Commission Decision provided for in Article 15 (1).

samples to be collected for Group A.

The balance will be allocated according to the experience and background information of the Member State.

Group B: 50 % of the total samples,

30 % must be checked for Group B 1 substances,

30 % must be checked for Group B 2 substances,

10 % must be checked for Group B 3 substances.

The balance will be allocated according to the situation of the Member State.

CHAPTER 3

Aquaculture products

1. Finfish farming products

A sample is one or more fish, according to the size of the fish in question and of the requirements of the analytical method.

Member States must respect the minimum sampling levels and frequencies given below, depending on the production of farmed fish (expressed in tonnes).

The minimum number of samples to be collected each year must be at least 1 per 100 tonnes of annual production.

The compounds sought and the samples selected for analysis should be selected according to the likely use of these substances.

The following breakdown must be respected:

Group A: one third of the total samples:

all the samples must be taken at farm level, on fish at all stages of farming(1), including fish which is ready to be placed on the market for consumption.

Group B: two thirds of the total samples:

the sampling should be carried out:

(a) preferably at the farm, on fish ready to be placed on the market for consumption;

(b) either at the processing plant, or at wholesale level, on fresh fish, on condition that tracing-back to the farm of origin, in the event of positive results, can be done.

In all cases, samples taken at farm level should be taken from a minimum of 10 % of registered sites of production.

2. **Other aquaculture products**

When Member States have reason to believe that veterinary medicine or chemicals are being applied to the other aquaculture products, or when environmental contamination is suspected, then these species must be included in the sampling plan in proportion to their production as additional samples to those taken for finfish farming products.

(6) Compounds included in Annex IV to Council Regulation (EEC) No 2377/90 of 26 June 1990

GROUP B — **Veterinary drugs** (1) **and contaminants**

(1) Antibacterial substances, including sulphonomides, quinolones

(2) Other veterinary drugs

- (a) Anthelmintics
- (b) Anticoccidials, including nitroimidazoles
- (c) Carbamates and pyrethroids
- (d) Sedatives
- (e) Non-steroidal anti-inflammatory drugs (NSAIDs)
- (f) Other pharmacologically active substances

(3) Other substances and environmental contaminants

- (a) Organochlorine compounds including PcBs
- (b) Organophosphorus compounds
- (d) Chemical elements
- (d) Mycotoxins
- (e) Dyes
- (f) Others

COMMISSION DECISION

of 14 December 2009

amending Annexes I and II to Decision 2006/766/EC establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted

(notified under document C(2009) 9870)

(Text with EEA relevance)

(2009/951/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption [1], and in particular Article 11(1) thereof,

Whereas:

(1) Regulation (EC) No 854/2004 provides that products of animal origin are only to be imported from a third country or part of a third country that appears on a list drawn up in accordance with that Regulation. It guarantee that those products exported to the European Union meet the sanitary conditions laid down in Union legislation to protect the health of consumers. Accordingly, Annex I to that Decision sets out a list of third countries from which imports of bivalve molluscs, echinoderms, tunicates and marine gastropods in any form for human consumption are permitted, while Annex II thereto sets out a list of third countries and territories from which imports of fishery products for human consumption in any form are permitted.

(4) Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council [4] lays down transitional measures for a period ending on 31 December 2009. Those measures include a derogation from Article 11(1) of Regulation (EC) No 854/2004, whereby Member States may authorise the import of bivalve molluscs and fishery products from

ANNEX

'ANNEX II

List of third countries and territories from which imports are permitted of fishery products for human consumption, other than those covered by Annex I to this Decision

(Countries and territories referred to in Article 11 of Regulation (EC) No 854/2004)

ISO code	Countries	Restrictions
AE	UNITED ARAB EMIRATES	
AG	ANTIGUA AND BARBUDA	Only live lobsters.
AL	ALBANIA	
AM	ARMENIA	Only live wild crayfish, heat processed non-farmed crayfish and frozen non-farmed crayfish.
AN	NETHERLANDS ANTILLES	
AO	ANGOLA	
AR	ARGENTINA	
AU	AUSTRALIA	
AZ	AZERBAIJAN	Only caviar.
BA	BOSNIA and HERZEGOVINA	
BD	BANGLADESH	
BJ	BENIN	
BR	BRAZIL	
BS	THE BAHAMAS	
BY	BELARUS	
BZ	BELIZE	

BR	BRAZIL	
BS	THE BAHAMAS	
BY	BELARUS	
BZ	BELIZE	
CA	CANADA	
CG	CONGO	Only fishery products caught, gutted (where appropriate), frozen and packed in their final packaging at sea.
CH	SWITZERLAND	
CI	COTE D'IVOIRE	
CL	CHILE	
CN	CHINA	
CO	COLOMBIA	
CR	COSTA RICA	
CU	CUBA	
CV	CAPE VERDE	
DZ	ALGERIA	
EC	ECUADOR	
EG	EGYPT	
ER	ERITREA	
FK	FALKLAND ISLANDS	
GA	GABON	

SH	SAINT HELENA Not including the islands of Tristan da Cunha and Ascension	
SN	SENEGAL	
SR	SURINAME	
SV	EL SALVADOR	
TG	TOGO	Only live lobsters.
TH	THAILAND	
TN	TUNISIA	
TR	TURKEY	
TW	TAIWAN	
TZ	TANZANIA	
UA	UKRAINE	
UG	UGANDA	
US	UNITED STATES	
UY	URUGUAY	
VE	VENEZUELA	
VN	VIETNAM	
YE	YEMEN	
YT	MAYOTTE	
ZA	SOUTH AFRICA	
ZW	ZIMBABWE'	

Imports of fishery and aquaculture products are only authorised from approved establishments (e.g. processing plants, cold stores) that have been inspected by the CA of the exporting country and found to meet EU requirements.

The CA provides the necessary guarantees and is obliged to carry out regular inspections and take any necessary corrective action.

A list of the approved establishments is maintained by the European Commission and published on its website.

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COUNTRY **Viet Nam**
PRODUCT **Fishery products**

Validity date from 25/08/2009
Date of publication 12/08/2009

00019

List in force

Approval number	Name	City	Regions	Activities	Remark	Date of request
DH 137	Canning Factory - Binh Chanh Foodstuff Company Limited (BCF Co., Ltd) - Special Aquatic Products Joint Stock Company (SEASPIMEX - VIETNAM)	Binh Chanh District	Ho Chi Minh City	PP	Aq	10/07/2009
DH 146	Pataya Food Industries (Vietnam) Ltd.	Binh Thuy	Can Tho City	PP		
DH 149	Highland Dragon Enterprise	Di An	Binh Duong	PP		
DH 165	Yuah Chyang Canned Food Company	Ben Luc	Long An	PP		
DH 174	Foodtech Co., Ltd	Ben Luc	Long An	PP		
DH 203	Ha Long Canned Food Stock Corporation - Halong Canfoco Canned Workshop 2	Nha Trang	Khanh Hoa	PP		
DH 226	Everwin Industrial Co. LTD	Thu Duc District	Ho Chi Minh City	PP		
DH 246	United Resources Cannery	Dien Khanh	Khanh Hoa	PP	Aq	
DH 323	Asia canned food factory, Asia Canned Products Import Export Company Limited	Chau Thanh	Tien Giang	PP	Aq	13/12/2007
DH 335	Kien Giang Joint - Stock Foodstuff Canning Company (KIFOCAN)	Chau Thanh	Kien Giang	PP	Aq	
DH 358	Phillips Seafood (Viet Nam) Co., Ltd	Dien Khanh	Khanh Hoa	PP	Aq	
DH 40	HaLong Canned Food Stock Corporation-Halong Canfoco	Ngo Quyen	Hai Phong City	PP		
DH 459	Trinity Viet Nam Co., Ltd (TRIVN)	My Tho	Tien Giang	PP		11/07/2008
DH 466	Royal Foods Co., Ltd.	My Tho	Tien Giang	PP		11/07/2008
DL 01	Seafood Joint - Stock Company No.1 - Seajoco Viet Nam	Tan Binh District	Ho Chi Minh City	PP	Aq	

COUNTRY **Bangladesh**
PRODUCT **Fishery products**

Validity date from 11/10/2009
Date of publication 28/09/2009

00017

List in force

Approval number	Name	City	Regions	Activities	Remark	Date of request
BAG-51	Bagerhat Sea Food Ind. Ltd.	Bahachat	Bahachat	PP	Aq	
BAG-76	Rupsha Fish & Allied Industries Ltd.	Bahachat	Bahachat	PP	Aq	
BAG-83	Shampa Ice & Cold Storage Ltd.	Bahachat	Bahachat	PP	Aq	
CDR-54	Sea Food Corporation Ltd.	Chandpur	Chandpur	PP	Aq	
CTG-31	SAR & Co. Ltd	Chittagong	Chittagong	PP	Aq	
CTG-32	Shrimp & Fish Processing Plant Ltd.	Chittagong	Chittagong	PP	Aq	
CTG-33	Meenhar Sea Foods Ltd	Chittagong	Chittagong	PP	Aq	
CTG-34	Chowdhury & Co. (BD) Ltd.	Chittagong	Chittagong	PP	Aq	
CTG-35	Apex Foods Ltd	Chittagong	Chittagong	PP	Aq	
CTG-36	Seamark (Holdings) Ltd.	Chittagong	Chittagong	PP	Aq	17/08/2009
CTG-38	Fish Preservers Ltd.	Chittagong	Chittagong	PP	Aq	
CTG-40	Meghna Sea Foods Ltd.	Chittagong	Chittagong	PP	Aq	
CTG-41	Mahi Fish Processing Ltd.	Chittagong	Chittagong	PP	Aq	
CTG-42	Anraj Fish Products Industries Ltd.	Chittagong	Chittagong	PP	Aq	
CTG-43	M H K Shipping Ltd	Chittagong	Chittagong	PP	Aq	
CTG-44	International Sea Food Ltd.	Chittagong	Chittagong	PP	Aq	
CTG-46	Coastal Sea Foods Ltd.	Chittagong	Chittagong	PP	Aq	

Inspections by the EC Food and Veterinary Office are carried out to confirm compliance with the requirements.

The inspection forms the basis of establishing confidence between the EC and the CA of the exporting country

EU border inspection of imports

Imports of fishery products from non-EU countries must enter the EU via an approved Border Inspection Post (BIP) under the authority of an official veterinarian.

Each consignment is subject to a systematic documentary check, an identity check and a physical check.

The frequency of physical checks depends on the risk profile of the product and also on the results of previous checks.

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Consignments which are found not to be compliant with the EU requirements are either destroyed or returned within 60 days.

Since 2004, EU government regulators, importers , processing plants and retailers have substantially increased aquaculture product testing for residues of veterinary medicines and other contaminants.

This has led to increased detections of trace levels of antibiotic residues, particularly nitrofurans and chloramphenicol in farmed shrimp consignments imported from various countries.

EU has a ‘zero-tolerance’ to the detection of these antibiotics in imported aquaculture products, resulting in numerous detentions, product recalls, international disputes, disruption of trade and, in some cases, large economic loss to the exporting countries and their industries.

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Publicity given to findings

This is mostly done through the
‘Rapid Alert System for Food and Feed’
for notification to other EU Member States and the EC

All findings published weekly by the EC

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RAPID ALERT SYSTEM FOR FOOD AND FEED

The legal basis of the system is Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (O.J. No L 31 of 1 February 2002).

The purpose of the rapid alert system for food and feed (RASFF) is to provide the control authorities with an effective tool for exchange of information on measures taken to ensure food safety.

To assist the members of the network, notifications are classified under three different headings[1]:

- **ALERT NOTIFICATIONS**

  Alert notifications are sent when a food or feed presenting a serious risk is on the market and when immediate action is required. Alerts are triggered by the Member State that detects the problem and has initiated the relevant measures, such as withdrawal/recall. The notification aims at giving all the members of the network the information to verify whether the concerned product is on their market, so that they also can take the necessary measures.

  Consumers can be reassured that products subject to an alert notification have been withdrawn or are in the process of being withdrawn from the market. The Member States have their own mechanisms to carry out such actions, including the provision of detailed information through the media if necessary.

- **INFORMATION NOTIFICATIONS**

  Information notifications concern a food or feed that was placed on the market for which a risk has been identified, but for which the other members of the network do not have to take immediate action, because the product has not reached their market or is no longer present on their market or because the nature of the risk does not require any immediate action.

- **BORDER REJECTIONS**

  These notifications concern food and feed consignments that have been tested and rejected at the external borders of the EU (and the EEA[2]) when a health risk was found. The notifications are transmitted to all EEA border posts in order to reinforce controls and to ensure that the rejected product does not re-enter the Community through another border post.

The Commission publishes a weekly overview of RASFF notifications belonging to the above three categories. As it is necessary to strike the balance between openness and the protection of commercial information, the trade names and the identity of individual companies are not published. This is not

Some examples of imported consignment rejection at the EU border

TABLE 3: BORDER REJECTIONS

Notifications in blue typeface concern feed, all other notifications concern food.

DATE	NOTIFIED BY	REF.	REASON FOR NOTIFYING	ACTION (TO BE) TAKEN
02/01/2009	Belgium	2009.AAA	prohibited substance nitrofuran (metabolite) nitrofurazone (SEM) (> MRPL) in frozen shrimps (Macrobrachium rosenbergii) from Bangladesh	product (to be) re-dispatched
02/01/2009	the Netherlands	2009.AAB	parasitic infestation of frozen frogs' legs from Indonesia	product (to be) re-dispatched
02/01/2009	the United Kingdom	2009.AAC	bad hygienic state of frozen fish from Brazil	product (to be) destroyed
02/01/2009	the United Kingdom	2009.AAD	bad hygienic state of frozen chicken popcorn and chicken zinger from Thailand	product (to be) destroyed
02/01/2009	Poland	2009.AAE	bad temperature control - rupture of the cold chain - of frozen white meat Pangasius hypophthalmus fillets from Vietnam	product (to be) destroyed
02/01/2009	Poland	2009.AAF	unauthorised establishment for frozen Alaska pollock fillets (Teragra chalcogramma) from China	product (to be) re-dispatched
02/01/2009	Poland	2009.AAG	unauthorised establishment for frozen Alaska pollock fillets (Teragra chalcogramma) from China	product (to be) re-dispatched
02/01/2009	Spain	2009.AAH	bad hygienic state of frozen fish from Mauritania	product (to be) re-dispatched
02/01/2009	Spain	2009.AAI	aflatoxins (B1 = 2.56 µg/kg - ppb) in almonds from the United States	product (to be) re-dispatched
02/01/2009	Spain	2009.AAJ	aflatoxins (B1 = 3.5; Tot. = 3.5 µg/kg - ppb) in almonds from the United States	product (to be) re-dispatched

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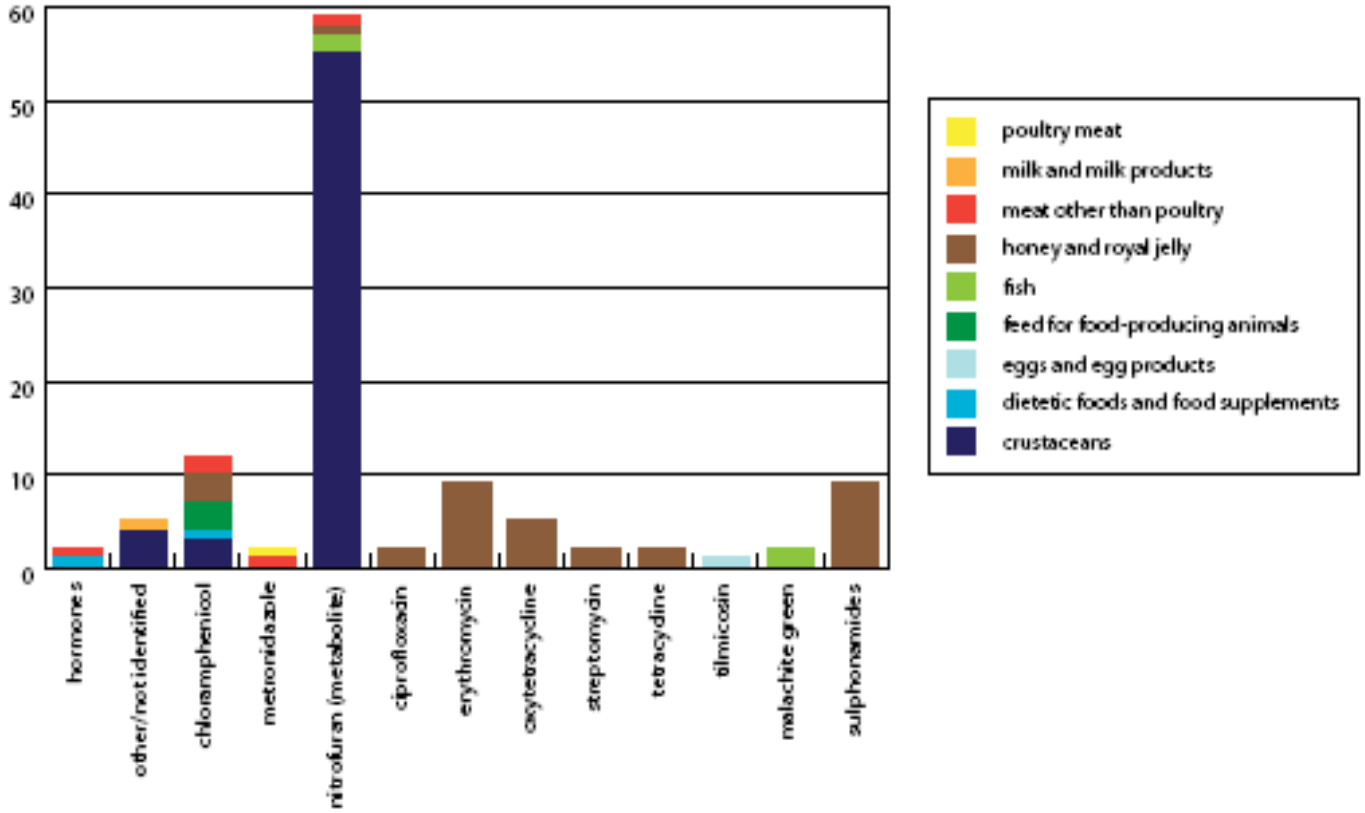
The Rapid Alert System for Food and Feed (RASFF)

Annual Report 2008

RASFF

Rapid Alert System for Food and Feed

RESIDUES OF VETERINARY MEDICINAL PRODUCTS



From the chart above it is obvious that nitrofuran metabolites are still the most-notified hazard in the RASFF in 2008, the large majority of findings made in crustaceans, predominantly shrimps from India (30) and Bangladesh (14). There is hardly any problem reported for residues in meat or fish but the

In 2008, the Bangladesh government banned the use of nitrofurans

May 2009

Bangladeshi exporters temporarily stopped shipping freshwater prawns (Macrobrachium) after traces of the banned antibiotic nitrofuran was found in some shipments to the EU.

The voluntary six-month suspension was imposed after EU countries had returned 50 container loads over the previous eight months. Could have led to total ban on imports of prawns from Bangladesh into all EU countries.

50,000 farmers in Bangladesh affected by the voluntary suspension.

Cefas

November 2009

Voluntary suspension withdrawn

So, has the problem been solved?

In Bangladesh there are:

~105,000 galda (Macrobrachium) farms

Increasing at rate of 10-20% per annum

~ 41,000 bagda (P. monodon) farms

Production increasing at about 20% per annum

Cefas

The minimum number of samples to be collected each year must be at least 1 per 100 tonnes of annual production.

The compounds sought and the samples selected for analysis should be selected according to the likely use of these substances.

The following breakdown must be respected:

Group A: one third of the total samples:

all the samples must be taken at farm level, on fish at all stages of farming(1), including fish which is ready to be placed on the market for consumption.

Group B: two thirds of the total samples:

the sampling should be carried out:

(a) preferably at the farm, on fish ready to be placed on the market for consumption;

(b) either at the processing plant, or at wholesale level, on fresh fish, on condition that tracing-back to the farm of origin, in the event of positive results, can be done.

In all cases, samples taken at farm level should be taken from a minimum of 10 % of registered sites of production.

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When Member States have reason to believe that veterinary medicine or chemicals are being applied to the other aquaculture products, or when environmental contamination is suspected, then these species must be included in the sampling plan in proportion to their production as additional samples to those taken for finfish farming products.

Is the EAFI concept a better approach?