



COMMISSION OF THE EUROPEAN COMMUNITIES

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**REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN  
PARLIAMENT**

**on the operation of Regulation (EC) No 304/2003 concerning the export and import of  
dangerous chemicals**

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### 1. INTRODUCTION

This report has been prepared in accordance with Article 21 of Regulation (EC) No 304/2003 of the European Parliament and of the Council concerning the export and import of dangerous chemicals<sup>1</sup>, hereinafter called the Regulation. The report covers the period from 2003 to 2005. It outlines the main provisions of the Regulation and the main tasks performed by the Member States, the Commission and industry, and it reviews implementation to date of the procedures including actions taken to improve the efficiency of the Regulation. The report also considers implementation problems that have been encountered and possible changes to the Regulation that could further improve its functioning.

The report is a summary of the information available from the Member States and the Commission as at 8 September. The full report is available on the Internet<sup>2</sup>.

### 2. BACKGROUND

#### 2.1. EC Regulation 304/2003

The Regulation came into force on 7 March 2003. Its main purpose is to implement the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, However the Regulation also contains a number of provisions that go significantly beyond the Convention's requirements. Moreover the rules apply to exports to all countries, not only Parties to the Convention.

#### 2.2. Designated National Authorities and overall administrative and legislative framework

Each Member State has its own Designated National Authority or Authorities (DNA(s)), but the Commission acts as the common DNA for the Community carrying out various administrative functions, as listed in section 2.3. The Commission also coordinates the Community input on all technical issues related to the Convention, at meetings of the Conferences of the Parties (CoP) and at meetings of the Chemical Review Committee.

More generally, the Commission is responsible for ensuring effective implementation of the Regulation. This includes handling of export notifications,

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<sup>1</sup> OJ L 63, 6.03.2003

<sup>2</sup> <http://ecb.jrc.it/edex>

import notifications and the timely exchange of information with DNAs and maintaining and developing the European Database on Export and Import (EDEXIM), managed by the European Chemicals Bureau at Ispra.

About 3.5 - 4 man years per annum are dedicated to this work.

Regular meetings are held with EU DNAs to discuss the Regulation's implementation and special ad-hoc expert meetings and other informal meetings held to tackle specific issues.

All Member States appear to have the necessary legislation and administrative systems for the implementation and enforcement of the Regulation. They have stipulated the DNA(s) responsible for the administrative functions required and provided for enforcement, including in most cases penalties for breach of the rules. Some Member States have different DNAs for industrial chemicals and pesticides.

The number of staff resources involved in implementation in each DNA varies between 0.15 to 1.25 man years. Most have been deployed on handling of export notifications, followed by requests for explicit consent.

In addition, additional resources from other authorities such as Customs offices assist with the implementation of the Regulation.

## **2.3. The main operative provisions and procedures of Regulation 304/2003**

### *2.3.1. Export Notification (Article 7)*

The EU export notification procedure currently applies to around 130 chemicals and chemical groups that are listed in part 1 of Annex I of the Regulation (as last amended by Commission Regulation 777/2006). This list comprises:

- chemicals that have been banned or severely restricted by Community legislation;
- chemicals that are subject to the PIC procedure ('PIC chemicals'), except those that are banned for export.

Each exporter must submit an export notification prior to the first export of a listed chemical at least 30 days before the export is due to take place, and at least 15 days before the first export in each subsequent calendar year. Export notification is required irrespective of the intended use of the chemical and whether or not that use is banned or severely restricted within the EU.

The notification is made to the exporter's DNA, which checks completeness and forwards it to the Commission. The Commission sends the first notification per chemical/importing country it receives each year as a Community export notification. The Commission registers all export notifications in EDEXIM.

The Commission follows up notifications in cases where there is no acknowledgement of receipt from the importing country. If necessary, a second copy of the notification is sent.

A preparation containing an Annex I chemical is also subject to notification, if the concentration of the chemical is such that it could trigger compulsory labelling under Community legislation. Also included in the procedure are articles or finished products containing chemicals in unreacted form that are subject to the PIC procedure or are banned or severely restricted in the Community within the meaning of the Convention.

#### 2.3.2. *Export notifications received from third countries (Article 8)*

When the Commission receives an export notification about a chemical from a third country, it registers this in the EDEXIM database and acknowledges receipt. The Commission forwards a copy of the notification and all available information to the DNA of the Member State concerned and, upon request, provides copies to other Member States.

In cases where a DNA in a Member State receives a notification directly, it must send it to the Commission, and the same procedure as above is followed.

#### 2.3.3. *Reporting of chemicals traded (Article 9)*

The exporter of a chemical listed in Annex I has to submit annual reports to his DNA of the quantities of that chemical exported to each importing country. Importers have to provide the same information for chemicals placed on the Community market.

Using this information, DNAs compile aggregate reports and send them to the Commission, which publishes an overall summary.

#### 2.3.4. *Submitting PIC notifications of regulatory actions to the Convention secretariat (Article 10)*

The Commission shall submit notifications of qualifying Community regulatory actions. Member States may also submit notifications of domestic regulatory actions via the Commission following consultation of the other Member States. Where regulatory actions do not qualify for notification, relevant information will be sent to the Convention secretariat under the Convention's information exchange provisions.

#### 2.3.5. *Adopting Community import decisions for chemicals subject to the PIC procedure (Article 12)*

The Commission shall adopt Community import decisions for PIC chemicals, where appropriate including in those decisions information of relevant national measures at the level of Member States.

#### 2.3.6. *The PIC procedure and explicit consent (Article 13)*

The PIC procedure currently applies to 41 chemicals or chemical groups listed in Annex III to the Convention (reproduced in part 3 of Annex I to the Regulation). The import decisions taken by Parties to the Convention regarding these chemicals are published every 6 months in the "PIC Circular".

The Regulation requires exporters to comply with these import decisions. In particular, export cannot proceed without the explicit consent of the importing

country, either through a positive import decision, or otherwise obtained from the importing country DNA by the exporting DNA. The explicit consent procedure applies to chemicals that are banned or severely restricted in the Community within the meaning of the Convention (listed in part 2 of annex I to the Regulation, which currently lists 31 such chemicals or chemical groups) but are not yet included in the PIC procedure.

In principle, obtaining explicit consent for a chemical is a one-off exercise. Once it has been obtained by one exporter's DNA, it should not be needed for subsequent exports, by any EU exporter, unless the terms of the consent obtained require otherwise.

#### *2.3.7. Export bans (Article 14)*

Chemicals and articles listed in Annex V, the use of which is completely prohibited in the Community, cannot be exported. Currently Annex V comprises mercury-containing soaps, and 10 chemicals or groups of chemicals listed in the Stockholm Convention on Persistent Organic Pollutants (POPs) in accordance with the provisions therein.

#### *2.3.8. Packaging and Labelling requirements (Article 16)*

All dangerous chemicals and preparations, whether or not they are banned or severely restricted within the EU, must be packaged and labelled for export as if they were to be marketed in the Community, i.e. the label and the accompanying safety data sheet should bear the same information, and where practicable, be in the importing country's language. In addition, the labelling requirements of the importing country have to be met. There are also specific requirements relating to expiry dates, size and packaging of containers, etc.

#### *2.3.9. Updating Annex I to the Regulation (Article 22)*

The Commission shall review the list of chemicals contained in Annex I at least every year on the basis of developments under Community legislation and under the Convention.

### **3. OPERATION TO DATE**

#### **3.1. Export notification**

Export notifications handled by Member States totalled 2273. The numbers have increased significantly between 2003 and 2005, from 223 to 1174 per year. About 55-60% concerned substances; the remainder preparations. The number of chemicals involved has doubled from 24 in 2003, to 54 in 2005. The total number of importing countries has also increased from 70 in 2003 to 101 in 2005.

Over 80% of the total number of notifications came from five Member States (Germany, UK, Netherlands, France and Spain). 10 Member States (Cyprus, Estonia, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Malta, Portugal and Slovakia) did not make any export notifications.

The total number of EU export notifications actually sent by the Commission was 1717 - 126 in 2003, 680 in 2004 and 911 in 2005. 200 sent notifications could not in fact be delivered (wrong email address, post address, etc.). In a high proportion of cases, the importing country fails to send an acknowledgement of receipt, as required by the Convention. In 2005, 532 notifications were re-sent. The Commission has expressed its concern on both issues at the Conference of the Parties to the Convention (CoP).

Acknowledgements of receipt obtained often include statements that consent to import is/ is not given, irrespective of whether or not explicit consent is required or has been sought, indicating a misunderstanding in some importing countries of the EU procedures.

### **3.2. Explicit consent**

A status list of explicit consents is maintained on EDEXIM. Member States can directly input data, although often importing countries respond to ECB, which adds the information. As at 10 February 2006, EDEXIM showed 478 requests having been made to 95 countries for about 20 different chemicals and 70 different preparations. Of these requests, involving 98 importing countries, most covered chemicals listed in part 2 of Annex I, i.e. those that are not PIC chemicals, with two such chemicals - Nonylphenols and Nonylphenol ethoxylates involved in about 60% of the cases. Overall at that time 239 explicit consents had been obtained and 15 requests for explicit consent had been refused, covering 12 chemicals/preparations and 11 countries. The remaining requests, some of which had been made in 2004, still awaited a response.

The actual number of cases is higher. The listing of explicit consents on EDEXIM was not introduced until 2004 so that some early cases may have been omitted. Moreover efforts have been made to delete overlapping or duplicate requests in those cases where consent has been obtained, although a number remain, largely due to some importing countries only allowing consent on a per shipment basis.

In many cases, the delay in obtaining responses to requests is caused by incorrect contact details for importing country DNAs. At the CoP, the Commission has consistently urged Parties to ensure that such information is kept up to date and encouraged the Convention secretariat to provide assistance to Parties to make import responses for chemicals subject to the PIC procedure.

The Commission has tried to assist Member States obtain explicit consents or sought clarifications from importing countries when responses have been unclear or provided them with additional information when requested. To facilitate responses, a standardised form for requests has been developed, available in English, French, Spanish and Russian. The Commission is also working on an explanatory note to be sent to importing countries with export notifications and requests for explicit consent to aid their understanding of the different procedures.

Guidance on how best to deal with cases, including possible options for alternative evidence that might be accepted in the absence of any response from the importing country, has also been included in detailed notes for guidance.

### **3.3. Export notifications from third countries**

The total number of export notifications received from third countries recorded on EDEXIM was 220. The actual figure is probably a little higher since some may have not been forwarded to the Commission or have otherwise gone unrecorded. Although notifications should go directly to the European Commission, most Member States still received notifications directly from the exporting countries. The main problem has related to notifications from the USA. Most Member States have requested the US authorities to send notifications to the Commission in future.

### **3.4. Experience with EDEXIM**

At the outset there were three versions of the database: one for the ECB/DG ENV, another for the DNAs of Member States, and a public "information" version. Many improvements have been made since then to meet users' needs. Most Member States consider that the system works smoothly and is very valuable as a tool for handling of export notifications and source of data and information.

There remain some problems, but many of these have been resolved or are being addressed. Work is well advanced in developing an "Enterprise" version that would enable exporters to electronically submit their export notifications for validation by their DNAs. A special version is also under development for customs authorities, who need a specific system to facilitate their work in controlling exports and imports in accordance with Article 17 of the Regulation. These plans are welcomed by Member States. ECB has provided users' guides and training for users. It has organised 7 training sessions and meetings with users to discuss improvements, including 2 meetings with customs experts.

### **3.5. Reporting on chemicals traded**

On the basis of reports provided by Member States, the Commission has produced overall summary reports for the years 2003, 2004 and 2005, all of which have been published on EDEXIM. An analysis for the period 2003 to 2005 is included in section 3.9 of the full report.

### **3.6. Updating of Annex I**

The Commission has regularly updated Annex I. The annex has been amended by Commission Regulations (EC) Nos 213/2003<sup>3</sup>, 775/2004<sup>4</sup> and No 777/2006<sup>5</sup>.

### **3.7. PIC notifications made**

To date the Commission has submitted notifications of EU regulatory actions for 12 chemicals. It has also forwarded notifications of national regulatory actions relating to a further 2 chemicals

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<sup>3</sup> OL L169, 8.7.2003, p.27

<sup>4</sup> OJ L123, 27.4.2004, p.27

<sup>5</sup> OJ L136, 24.5.2006, p.9

The Commission has also on several occasions informed other countries of Community regulatory actions that did not qualify for PIC notification.

### **3.8. Import decisions for PIC chemicals**

The Commission has adopted the following decisions establishing Community import responses for chemicals subject to the PIC procedure: Decision 2003/508/EC<sup>6</sup>, Decision 2004/382/EC<sup>7</sup>, Decision 2005/416/EC<sup>8</sup>, and Decision 2005/814/EC<sup>9</sup>.

In addition, a number of previous import responses were extended without changes to all EU 25 Member States following the 2004 enlargement.

### **3.9. Compliance and enforcement activities**

Overall there seem to have been no major infringements of the Regulation.

Most Member States reporting infringements did not impose sanctions but issued warnings and planned closer monitoring in future. In most cases, non-compliance was either detected by the customs officers or when companies had submitted their yearly reports on quantities exported and corresponding export notifications were found to be lacking.

### **3.10. Awareness-raising**

All Member States and the Commission have provided information to industry, usually through training sessions, seminars, workshops, bulletins, etc. Similar consultations and training are provided by some Member States for customs officers.

Draft detailed technical notes for guidance for DNAs have been published on EDEXIM. The Commission has published a guide to the Regulation in all EU languages. Most DNAs have created a web page on the Regulation including the national language version of the Regulation and the guide.

The Commission has given presentations to DNAs in importing countries to help improve their understanding of the EU procedures. Some Member States have engaged in information programmes with third countries including seminars and study tours.

## **4. IMPLEMENTATION PROBLEMS AND POSSIBLE IMPROVEMENTS**

### **4.1. Customs controls**

Most Member States consider that enforcement at border controls is important and that there is a need for closer collaboration and regular exchange of information between DNAs and customs officers.

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<sup>6</sup> OJ L174, 12.7.2003, p.10

<sup>7</sup> OJ L199, 7.6.2004, p.7

<sup>8</sup> OJ L 147, 10.6.2005, p.1

<sup>9</sup> OJ L 304, 23.11.2005, p.46



Article 17 of the Regulation is generally worded and is rather weak. Most Member States would like to see clearer provisions, including specific obligations on exporters and the appropriate tools that would facilitate the work of customs in controlling exports and imports.

In response to these concerns, work is well advanced in classifying chemicals subject to Annex I to the Regulation within the Combined Nomenclature (CN) and in including 'warning flags' in the Integrated Tariff of the European Communities (TARIC) against the relevant CN CN codes that would alert customs officers to the fact that the chemicals concerned are or could be subject to special rules. In addition, linked to the development of a customs version of EDEXIM to meet the specific needs of customs officers, work is also well advanced in providing in TARIC for unique identification codes generated by EDEXIM for export notifications made, explicit consents obtained etc that could be used by exporters in section 44 of the export declaration form (the Single Administrative Document) to show that the rules have been respected and that could be readily verified by customs officers by checking on EDEXIM.

However there is general agreement that for such a system to be fully effective, the use of these special identifier codes should be made mandatory.

#### **4.2. Explicit consent**

Several Member States are experiencing problems with the procedure, particularly difficulties in getting timely responses from importing countries. In about half of the cases, despite the efforts of exporting DNAs and the Commission, no response to requests has been obtained, in some cases after many months or years, despite the fact that often it is known that use of the chemical is allowed in the importing country concerned. This often results in exports being unable to proceed from EU countries, but can be made by other countries (because they do not need to obtain explicit consent for these substances), thereby disadvantaging EU exporters. The number of cases involving such delays is significantly higher than could have been foreseen when the Regulation was adopted and the work involved for the Member States concerned and the Commission is much greater than anticipated. Part of the problem is incorrect contact details; another appears to be lack of understanding of our procedures. The latter applies especially to chemicals that are not PIC chemicals and fall only in part 2 of annex I, which is often confusing to third countries.

Providing information in the language of the importing country might improve the situation. Greater efforts to help importing countries respond to requests, with the Commission being more involved including in a co-ordination role, may also help. The Commission has already taken such actions where possible and will continue to do so. These have had some effect. However overall the situation has not improved significantly and is unlikely to do so in the future without further measures.

Some Member States would favour abolishing the explicit consent requirement for chemicals in part 2 of Annex I; or failing that, revising the criteria for including chemicals in that part of Annex I. However the emerging consensus is that perhaps the best solution would be to maintain the procedure, but follow an approach whereby in cases where no response were to be received, subject to certain

conditions export could proceed as a temporary solution while further efforts are made to obtain consent.

In addition, the possibility of channelling all requests for consent through the Commission could be explored subject to the necessary resources being available. This would help to prevent any unnecessary overlaps or duplication of effort and may also help to avoid possible misunderstandings and confusion in importing countries., which receive export notifications from the Commission (via ECB) and requests for consent directly from the Member States.

#### **4.3. Other points**

Greater clarity is needed in the scope of the rules relating to export notifications (and where applicable explicit consent) in respect of preparations. This issue is already covered in the detailed notes for guidance for DNAs, which make it clear that preparations are only subject to the export notification and explicit consent requirements (where applicable) when they contain a chemical(s) listed in the relevant part(s) of Annex I of the Regulation to the extent that its presence is such that it could trigger labelling, irrespective of the presence of any other substances in the preparation. This should be reflected in the Regulation itself.

It has been suggested that export notifications should include information about the expected quantities of export each year so that the importing country has a clearer overall picture. Making clearer the intended use in export notifications would also be helpful. Often importing countries request further information of these kinds.

The Regulation's definition of 'exporter' can give rise to some problems in relation to the export notification requirement for goods that are delivered by EC manufacturers or distributors to non-EU based traders who then export the goods. This has been addressed in the detailed notes for guidance for DNAs, but needs to be covered in the Regulation itself so that there is a harmonised approach.

The procedure for handling export notifications from third countries is not optimal. The majority of these notifications come from the USA. Hopefully, once the US starts sending all the notifications directly to the Commission, the procedure will function more smoothly.

Several Member States commented on the difficulties of obtaining information on imports of Annex I chemicals, linking this to the procedure for export notifications from third countries. However such notifications normally do not relate to Annex I chemicals so information contained therein is unlikely to help Member States in fulfilling their reporting obligations. One comment was that the provision be dropped. However such information aids transparency and is useful for monitoring purposes to assess the impact and effectiveness of the Regulation and Community chemicals legislation more generally.

## 5. CONCLUSIONS

Regulation 304/2003 has been in operation for 3 years. During this time the workload for the DNAs has increased as exporters have become more familiar with the rules and more chemicals have been added to the different procedures. Overall the amount of DNA resources involved is not significant. The administrative burden for exporters and the authorities remains reasonable, although some authorities have encountered problems. The workload will continue to increase, but overall this should not prove unduly burdensome provided that the necessary resources continue to be available at national and EU level.

Overall the procedures of the Regulation have proved effective and functioned well. The main problem has been the delays in obtaining responses to requests for explicit consent. The number of such cases is much higher than could have been anticipated causing additional workload. It has added significantly to the administrative burdens on exporters, DNAs and the Commission. It has also disadvantaged EU exporters vis-à-vis competitors without necessarily adding to the protection of human health and the environment in importing countries. The situation as regards chemicals listed in part 2 of Annex I is particularly problematic.

Although there were initial problems with EDEXIM caused by difficulties in adapting the database to accommodate all the Regulation's requirements in full and meeting user's needs, much progress has been made in addressing these problems. In particular, the planned 'Enterprise' version will simplify and speed up the process.

Co-operation between Member States and the Commission is excellent. Generally the information circulates smoothly between the different parties. However the flow of information with importing countries could be improved.

To date there appear to have been no major problems of non-compliance with the rules.

The importance of enforcement has been emphasised, in particular the role of customs authorities in this regard. Closer collaboration with customs is needed. There is also widespread support for additional tools to help facilitate the work of customs control, particularly as regards exports.

There are also a number of more minor issues where the scope of the rules could be clarified.