Notification of New Chemical Substances Under the Seventh Amendment of the European Union’s Dangerous Substances Directive


Regulatory Background

Since 1967, chemical substances have been regulated in the EU under the DSD. The DSD has been amended several times. The Sixth Amendment to the DSD (79/831/EEC) introduced reporting requirements for chemical substances that were in European commerce prior to September 18, 1981. All substances so reported were listed on the European Inventory of Existing Commercial Chemical Substances (EINECS). Substances listed on EINECS can be marketed in the EU without prior notification under the DSD.

In 1992, the DSD was amended for the seventh time (92/32/EEC). The Seventh Amendment requires any person planning to market in the EU a “new substance” (e.g., a chemical substance not listed on EINECS) to first submit a new substance dossier to the member country in which the substance will first be “placed on the market.” EINECS is a closed list; new substances are not added to EINECS when they are notified. New substances, once reviewed, are added to the European List of Notified Chemical Substances (ELINCS), which is published from time to time in the Official Journal of the European Communities. ELINCS is helpful to review in that it assists notifiers in identifying substances that have already been notified and the potential for data sharing. However, ELINCS-listed substances may not be manufactured or imported by a different party without being re-notified. In this way, EU chemical notification today is handled much like an individual licensing process.

With respect to substances that are manufactured outside the EU (i.e., substances imported into an EU member country), the Seventh Amendment provides two options for the notifier: (1) a substance may be notified by the importer; or (2) the substance may be notified by a person in the EU designated by the manufacturer as the manufacturer’s sole representative. The sole representative procedure obviates the need for a substance manufactured by a single manufacturer, but imported by several importers in the EU, to be repeatedly notified. Specifically, if a sole representative is appointed, a substance can be imported directly into any member country following notification. Sole representatives take on all responsibilities of the notifier.

The DSD generally requires a “base set” of test data as part of the premarket notification package. The specific
data requirements potentially applicable to notification of new substances and new polymers under the Seventh Amendment are found in Annex VII of the Directive. Studies should be conducted in accordance with the protocols described in Annex V of the Directive, which closely follow corresponding Organization for Economic Cooperation and Development (OECD) guidelines.

Tracking import volume is critical to staying in compliance with this law. Reduced data requirements apply for lower quantity imports, and the amount and complexity of the data that a company must submit increases as the import volume increases. A manufacturer must notify the CA once it exceeds certain quantity thresholds. However, the substance may continue to be marketed in the EU while subsequent data requirements are being met. Additionally, Article 7.1 of the Seventh Amendment requires submission of all relevant, available data on the substance as part of the notification.

The EU allows data sharing for “duplicate” notifications for essentially the same chemical substance. The EU also has a procedure for seeking permission for “read across” data treatment for similar, but not duplicate, notifications. The procedure involves making a request to the relevant CA for permission to use data from testing one chemical substance for the purpose of notifying and indicating the toxicological properties of a related substance or group of substances. The CA will make a decision based on the merits of the request.

After submitting a technical dossier, the standard CA review time is 60 days. Individual country approvals are mutually recognized by member countries in the EU. Following the review period, the country that accepts the dossier notifies the EU and other Member States of the approval, and marketing of the product in the other member countries may proceed during this process. Even though marketing may proceed, another country may ask that the base set of data be supplemented, and negotiations would have to occur on the additional requests for data.

• **Statutory Exclusions**

The Seventh Amendment has statutory exclusions from its coverage. See Article 1(2). These exclusions apply to the following preparations in the finished state, intended for the final user:

• medicinal products for human or veterinary use, as defined in Directive 65/65/EEC (10), as last amended by Directive 87/21/EEC (11);

• cosmetic products defined by Directive 76/768/EEC (12), as last amended by Directive 86/199/EEC (13);

• mixtures of substances which, in the form of waste, are covered by Directives 75/442/EEC (14) and 78/319/EEC (15);

• foodstuffs;

• animal feedingstuffs;
▪ pesticides;

▪ radioactive substances as defined by Directive 80/836/EEC (16);

▪ other substances or preparations for which Community notification or approval procedures exist and for which requirements are equivalent to those laid down in this Directive.  

The exclusion for cosmetics is limited to finished cosmetics products, and does not apply to cosmetic ingredients, which must be notified.  

Food additives are excluded from notification under the exclusion for “foodstuffs.” In addition, the Seventh Amendment does not apply to the carriage of dangerous substances by rail, road, inland waterway, sea or air; or substances in transit that are under customs supervision and that do not undergo any treatment or processing.

▪ Notification Thresholds and Data Requirements

The attached table, “European Union (EU) New Chemical Substance Notification Requirements” summarizes the EU notification thresholds, corresponding data requirements, notification fees, and data development costs based on laboratory estimates. The Seventh Amendment provides for several reduced notification categories for imports of less than 1 metric ton/yr. New data are not required to be developed for substances imported in quantities less than 10 kg/yr.

For larger volume imports, the “base set” data requirements of Annex VII.A apply, which include information on the identity, production, and physical properties of the substance, as well as at least two acute mammalian toxicity studies, a repeated dose study, two mutagenicity studies, two acute ecotoxicological studies (fish and Daphnia), algal growth inhibition, and three degradation studies. This level of notification permits import of the product up to 10 metric tons/yr.

Once import volumes reach the “Level 1(A)” threshold of 10 metric tons/yr, the manufacturer is required to notify the CA that the threshold has been reached. However, the manufacturer is not required to cease its introduction of the chemical once the Level 1 threshold is triggered and notification is made. Additional testing requirements, if any, may include some of the Annex VIII, Level 1 tests. Required tests are negotiated with the CA through a process that can take several months, or even up to a year. Most importantly, if VII.A “base set” testing has been completed, the chemical can continue to be manufactured or imported above the Level 1 threshold during the negotiation process and the testing period.

Notification and more extensive submission of the data in Annex VIII, Level 1 are required if the 100 metric tons/yr threshold is triggered. Specifically, “Level 1(B)” may require fertility studies, a teratology study, a subchronic or chronic study, additional mutagenicity studies, and additional ecotoxicological studies.

As is the case when the Level 1 threshold is triggered, an additional notification must be made when the Level 2 threshold of 1,000 metric tons/yr is triggered. Similarly, introduction of the chemical need not cease when the threshold is triggered and can continue while the CA decides what testing is required and during the testing period. Annex VIII, Level 2 generally requires a chronic study, a carcinogenicity study, and additional
ecotoxicological studies.

- Polymers

- "Two-Percent Rule"

The EINECS status of a polymer is determined by the EINECS status of the monomers and reactants which comprise the polymer. Under Article 13(2) of the Seventh Amendment, polymers are considered as notified under the DSD unless they contain in combined form two percent or greater of any substance that is not listed on EINECS. The corollary to this is that if the monomers and reactants used at two percent by weight or greater in the manufacture of a polymer appear on EINECS, the polymer is considered to be implicitly listed on EINECS. Thus, polymers, per se, do not appear on EINECS, but not need to be notified under the Seventh Amendment if they are manufactured from EINECS-listed monomers and reactants.

- Notification of Polymers

Commission Directive 93/105/EC (OJ L 294/31 (Nov. 30, 1993)) provides the base set testing requirements which must accompany technical dossiers for the notification of polymers. The Directive implements these requirements as Annex VII.D to the Seventh Amendment. For reportable polymers, Annex VII.D allows for the testing of representatives of families of polymers, rather than of all polymers of a given family. It also establishes criteria to distinguish between polymers with high molecular weight, for which a reduced base set test package will be deemed sufficient, and other polymers that will require a full base set submission.

A polymer for which a reduced test package is acceptable must meet some or all of the following criteria.

- It must be "non-readily degradable."
- It must have a high number average molecular weight. No specific molecular weight is provided in the Directive; instead it is left to the CA's receiving the notification.
- It must have extractivity in water of less than 1 mg/l.
- It must have less than 1 percent of species below a molecular weight of 1000.

The polymer-specific "base set" requirements will also vary depending on the amount of the polymer to be introduced into commerce. For polymers that require a full "base set" submission, the data called for in Annex VII.D are required in addition to, and not as a substitute for, the information and tests required in Annex VII.A, B, or C. For polymers that meet the reduced "base set" criteria, the data called for in Annex VII.D are submitted in
The Seventh Amendment introduced important changes with respect to polymers. By design, EINECS, which was compiled under the Sixth Amendment to the DSD, excluded “polymers,” “polymerizates,” “polycondensates,” and “polyadducts" per se. 13 When the EU adopted a definition of “polymer,” discussed above, as part of the Seventh Amendment, the status of substances that did not satisfy the new polymer definition but have been exempted from reporting under EINECS as “polymers,” “polymerizates,” “polycondensates,” and “polyadducts” was called into question.

To remedy this problem, a no-longer polymers list (NLPL) was developed to provide a safe harbor for substances that, although previously excluded from EINECS as “polymers,” would no longer have such status. 14 NLP status is essentially a “grandfathered” status for polymers that were already in commerce when the Seventh Amendment polymer definition was adopted and that no longer qualify as polymers. 15 The EU continues to accept notifications to the NLPL. Companies are permitted to make their own NLP determination, although the CAs prefer that companies submit notifications of their NLP determinations. 16 To be considered an NLP, a substance:

• could have been considered to be a polymer under the 6th Amendment definition;
• is not a polymer under the Seventh Amendment definition; and
• must have been placed on the EU market between September 18, 1981 and October 31, 1993 (inclusive).

The Manual of Decisions provides that polymers created from (1) NLPs only; or (2) NLPs and EINECS-listed substances, are exempt from notification under the DSD. 17

• REACH

The future of chemical control regulation in the EU will likely be significantly affected by a proposed new regulatory framework adopted by the European Commission on October 29, 2003. The objective of this reform, known as “REACH” (Registration, Evaluation, and Authorization of Chemicals), is to deal with the chemical “burden of the past” by establishing a single system to govern both “new” and “existing” substances above 1 metric ton. 18

The attached flowchart provides an overview of the proposed REACH legislation. Under this system, companies would be required to submit data for substances manufactured or imported in excess of 1 metric ton/yr and register the substances in a central database. A chemical safety assessment would have to be completed for substances manufactured or imported in quantities of 10 metric tons/yr or more. The proposed legislation does
provide for data sharing, so new testing will be required only if insufficient information on the substance is available. The data requirements for chemicals imported in quantities of 10 to 100 metric tons/yr are comparable to the current requirements under the DSD.

If there is reason to believe a substance may present a risk to human health or the environment, the substance may be subject to evaluation, during which additional information may be required and use restrictions may be imposed. Authorization would be required for before certain substances, including CMRs (substances that can cause cancer or mutations, or are toxic to reproduction) and PBTs (persistent, bioaccumulative and toxic chemicals), could be manufactured or imported into the EU.

The proposed REACH legislation is under consideration for adoption by the European Parliament and the EU's Council of Ministers, and binding legislation could be in place by 2005. European Union (EU) New Chemical Substance Notification Requirements

<table>
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<tr>
<th>Threshold (kg/yr)</th>
<th>Review Period(days)</th>
<th>Summary of Data Requirements</th>
<th>Data Development Time</th>
<th>Estimated Data Costs (U.S.$)</th>
<th>Estimated Filing Fees</th>
</tr>
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<tr>
<td>&lt; 10</td>
<td>30</td>
<td>No more than points 1 and 2 of Annex VII.C, no new data required. Estimate one to several weeks required to research, compile, and redact relevant existing test data. No toxicology data costs attributable to this submission. Filing fees: £540+ £540 (risk assessment fee if necessary)+ £94.50 VAT Total: £1175 H $1,762 (U.S.)</td>
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<tr>
<td>10 - &lt; 100</td>
<td>30</td>
<td>Annex VII.C e 10 - &lt; 100 30</td>
<td>Annex VII.C</td>
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</tbody>
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- chemical identity information
- spectral data
- analytical determination methods
- estimated production levels for first three years
- use, handling, distribution, and disposal information
- physicochemical properties data
- either an acute oral or acute inhalation toxicity study

Physicochemical tests: less than one month.
Acute toxicity testing: One to two months. $4,000 Filing fees: £540+ £540 (risk assessment fee if necessary)+ £94.50 VAT Total: £1175 H $1,762 (U.S.) Annex VII.B e 100 - < 1 metric ton/yr, or accumulated total of e 500 kg - < 5 metric tons 30 Annex VII.B

- additional physicochemical property data
- skin and eye irritation and skin sensitization
- mutagenicity
- Physicochemical tests: less than one month.

Acute toxicity testing, skin irritation, skin sensitization, biodegradation and genotoxicity: one to two months. $25,000-$35,000 Filing fees: £935+ £540 (risk assessment fee if necessary)+ £94.50 VAT Total: £1570 H $2,355 (U.S.) Annex VII.A e 1 - < 10 metric ton(s)/yr, or accumulated total of e 5 kg - < 50 metric tons 60 Annex VII.A ("base-set")

- chemical identity
- production information
- physical properties information
- at least 2 acute mammalian toxicity studies
- a repeated dose study
- mutagenicity studies
- acute ecotoxicological studies
- degradation studies 7-8 months

(approximately 1 year total time for testing, notification and review process) $100,000 - $150,000 Filing fees: £4630+ £2,200 (risk assessment fee if necessary)+ £388.50 VAT Total: £7,218 H $10,827 (U.S.) Level 1(A) (10 t) e 10 - < 100 metric tons/yr, or accumulated total of e 50 - < 500 metric tons 60 Annex VII.A and some or all of Annex VIII
Level 1 tests may be required. Development time depends on type of tests negotiated with Competent Authority; however, if VII.A testing is complete, introduction of the substance can continue during the Level 1(A) testing period. Depends on type of tests negotiated with Competent Authority.

$0 - $50,000 (in addition to VII.A test costs, broad estimate) Filing fees: £2,430 H $3,645 (U.S.) (in addition to VII.A fees) Level 1(B) (100 t) e 100 - < 1,000 metric tons/yr, or accumulated total of e 500 - < 5000 metric tons 60 Annex VII.A, Annex VIII, Level 1

- fertility studies
- teratology study
- subchronic or chronic study
- additional mutagenicity studies

- additional ecotoxicological studies. Development time difficult to predict; however, if VII.A testing is complete, introduction of the substance can continue during the Level 1(B) testing period. $150,000 (in addition to VII.A test costs, broad estimate) Filing fees: £4,780 H $7,170 (U.S.) (in addition to VII.A and Level 1(A) fees) Level 2 (1000 t) e 1,000 metric tons/yr, or accumulated total of 5,000 metric tons 60 Annex VII.A, Annex VIII, Level 2

Production volumes this high have rarely been reported in the EU; thus, the testing requirements at this level are not predictable. Tests that can be required include:

- a carcinogenicity study
- a fertility study
- additional ecotoxicological studies. Difficult to predict. Dependent on testing required; however, if VII.A testing is complete, introduction of the substance can continue during the level 2 testing period. 22 Difficult to predict. Depends on testing required Filing fees: £3,350 H $5,025 (U.S.) (in addition to VII.A, Level 1(A), Level 1(B) filing fees)

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This document was last updated January 2004. See http://ecb.jrc.it/new-chemicals/.


Under the Seventh Amendment, a transfer between two companies, even if they belong to the same group, is considered “placing on the market,” whereas transfer between two factories operated by the same company is not. Transfers between employees of the same company are not included so long as the employees act on behalf of the employer, not independently. The definition covers all transfers of control, not only those which are accompanied by transfer of ownership. Transfer to a processor, for instance, is therefore covered by the definition. In contrast, holding in stock by the manufacturer is not considered “placing on the market,” nor is manufacture of a site-limited intermediate.

Articles 10.1 and 16.2 of the Seventh Amendment.

See Articles 5, 14, and 17 of the Seventh Amendment.

In accordance with Article 29(4)(a), the Commission is required to establish a list of such substances and preparations to be periodically reexamined and revised as necessary.

MOD at Section 5.4.

MOD at Section 5.3.

The term “combined form” refers to chemically reacted. The term “polymer” is defined as a substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. In the context of this definition a “monomer unit” means the reacted form of a monomer in a polymer.

All of the criteria must be met for polymers marketed in quantities of 1 metric ton/yr (or total quantity of 5 metric tons) or more. Only the first and second criteria must be met for polymers marketed in quantities below
these thresholds.


15 Within the set of substances that were not reported for EINECS there may be a subset of substances that are not no-longer polymers: "never-were polymers." These are substances that are not listed on EINECS and were introduced into EU commerce without benefit of a notification because they were omitted or because the substances in question were incorrectly classified as "polymers" under the undefined standards of the Sixth Amendment yet do not qualify as no-longer polymers. We understand that NLPL submitters will be challenged concerning substances that are reaction products or adducts with no plausible claim to being polymers.

16 MOD at Section 5.6.7.2.1.

17 MOD at Section 5.6.6.2.


19 This table provides an overview of notification requirements for non-polymeric substances under the EU Dangerous Substances Directive (DSD), Directive 67/548/EEC of 27 June 1967, OJ L 196/1. Polymer-specific data requirements are detailed in Annex VII.D of the DSD.

20 Filing fees vary according to the Member state in which the notification is made. For reference purposes, the filing fees for the United Kingdom are included in this chart. The estimated fees shown do not include legal/consulting fees that may be required.

21 Once the Level 1 threshold is triggered, the manufacturer or importer is required to notify the Competent Authority (CA) that the threshold has been reached. Any additional testing requirements are then negotiated with the CA, which may require some of the tests in Annex VIII, or may require no additional testing at all. A laboratory in the U.K. with whom we spoke indicated that it is unlikely for required additional data costs at this level to exceed $50,000 (U.S.). The testing negotiation process can take several months, or even up to a year. However, the manufacturer or importer is not required to cease its introduction of the chemical once the Level 1 threshold is triggered and notification is made. If VII.A “base set” testing has been completed, the chemical can continue to be manufactured or imported above the Level 1 threshold during the negotiation process and the testing period.

22 As is the case when the Level 1 threshold is triggered, an additional notification must be made when the Level 2
threshold is triggered. Similarly, introduction of the chemical need not cease when the threshold is triggered and can continue while the CA decides what testing is required and during the testing period.