6 October 1997

Guidance document for the implementation of Annex VII D of Council Directive 67/548/EEC (Directive 93/105/EEC)

1. Introduction

The Directive 93/105/EEC[1] contains a specific test strategy for polymers. In addition to the test package, in analogy to Annex VII of Directive 67/548/EEC, it incorporates a concept for grouping polymers (including the family approach) and provides the concept of a reduced test package for polymers fulfilling various specific criteria. This guidance describes those concepts but has no legal status. It is intended to clarify notification of polymers.

2. Test package for polymers and testing methods

2.1 Test package

The test package for polymers consists in principle of the normal test programme according to Annexes VII and VIII supplemented by some polymer-specific tests (but with the potential for no or fewer tests, as in sections 4 and 5 of the Directive and the scheme in figure 1). These tests permit the identification of substances as polymers in compliance with the polymer definition (cf. Art. 2, para 1 c of the Directive 67/548/EEC; number-average molecular weight, molecular weight distribution, identity and concentration of the starting monomers and starting substances which will be bound in the polymer). They also allow the performance of hazard assessment for polymers (based on indications of endgroups, identity of reactive functional groups, identity and percentage of main impurities and non-reacted monomers, statement concerning the intended environmental degradability with relevant information, extractivity in water and cyclohexane) on the assumption that possible effects should be mainly due to the low molecular weight and soluble components. The tests at different pH-values in water are designed to reflect varying physiological/environmental conditions.

Additionally in certain cases and without delaying the decision on the acceptability of the notification, ecotoxicologically relevant test (light-stability, long-term extractivity) may be required if there is an exposure potential to man or environment.

The test for light-stability provides information about a potential danger to the environment as a result of the possible formation of reaction products. For polymers that are only placed on the market containing light-stabilizers this test provides no relevant information and should be omitted.

The long-term environmental extractivity should be estimated by leachate tests. The leachate test should reflect the fate of polymers in the environment (e.g. on waste disposal sites). Depending on the results of the leachate test, i.e. if the leachate is formed in relevant amounts (criteria to be developed), appropriate ecotoxicological tests on the leachate (e.g. acute toxicity test on either fish, Daphnia or algae, appropriate biodegradation test) may be requested on a case by case basis.

2.2 Testing methods

[1] OJ L 294, 31.11.1993, p.21

Wherever possible, testing methods described in Annex V of Directive 67/548/EEC must be used. Where such methods are not available or are not appropriate, other internationally recognized methods are accepted, with appropriate justification. Thus the tests for molecular weight distribution, Mn(*) (by gel permeation chromatography or physico-chemical methods), % species with $M^+ < 1000$, and water extractivity generated by EU/OECD officials and available in draft-form May 1994 (and already in use) are due to be published by the EU during 1997. For test 3.1.6 under section C2.1 of the Directive (93/105/EEC), OECD test 113 can be used and for the leachate test, above, a UK draft method is available.

3. Grouping polymers

While maintaining the basic principle of 1 substance - 1 notification, there will be the possibility for notifiers to submit one technical dossier which will cover several polymers which are proposed to be marketed. This grouping is possible at two levels, covering (3.1 below) a narrow and (3.2) a wide range of variation.

3.1 Meaning of "substance"

In the particular case of polymers, the term substance is taken to mean a narrow group of (co)polymers of similar composition and/or similar Mn(*) values, even if the small variations are due to deliberate alterations to the process conditions, the process itself remaining unchanged.

Small variations include the following:

a) for homopolymers, the Mn can vary by up to 3-fold;

b) for co-polymers where,

(i) the Mn remains approximately constant (variation up to 2-fold) while the composition varies by ± 10% absolute.

or

(ii) the composition remains approximately constant (variation up to ± 3% absolute) while the Mn can vary up to 3-fold.

Each substance, as defined above, will be subject to one notification, with as a consequence, the cumulation of the tonnages, one entry in ELINCS etc. For (a) and (b) (ii), the tests are done on the polymer with lowest Mn (Examples 1 & 7) and for (b) (i) that with the mean composition.

In any case, information on the identity and quantities of the different polymers which are actually marketed and covered by the same substance definition, will need to be made available to the Competent Authorities. Examples are given in Annex 1

(*) Mn is number average molecular weight
+ M is molecular weight

Where a group of polymers to be marketed is too wide in composition or Mn to be a "substance", then it may be possible to consider the group as a "family", as follows:

3.2 Family approach

The concept of grouping polymers into families is based on the assumption that, in principle, the members of a family of polymers process a similar hazard potential. The decision to group polymers into a family is not mandatory and is left to the notifier.

A family of polymers is defined as a group of polymers/substances (in the meaning of 3.1), either homopolymers or copolymers, in which one parameter, e.g. the number-average molecular weight, Mn, is "fixed" while one (NB one) other (e.g. the composition) is allowed to vary, due to the differing ratios of monomer units, over a relatively large range. In this concept, "fixed" means confined to a narrow range consistent with the possibly wide variation of the variable parameter. In this and similar examples the variation in the Mn values or in the composition is due to not unintentional process-related fluctuations but to deliberate alterations to the process conditions, the process itself remaining unchanged. Another example would be where the same polymer chain is attached to a series of side-chains of varying length as in Annex 1 example 8, or to a series of closely related, for example, carbohydrates. Other examples may be possible but the prospective notifier should first enquire of the local Competent Authority.

It is assumed that the low molecular weight members of the family produce greater toxicological and/or ecotoxicological effects than the high molecular weight members because of their higher solubility and mobility. Although it is recognized that the effects might not be always linear throughout the family, testing of polymers on a family basis is accepted in order to reduce technical dossiers and tests to a reasonable and yet sufficient number.

The concept consists of testing representative members of the family. For example for a family with composition fixed, Mn varying i.e. of homopolymers (i.e. in contrast to a "substance" under 3.1(a), Mn extending over more than a 3-fold range), the notifier proposes the Number average molecular weight range of the family and submits, in the first instance, two technical dossiers one for each end of the family. In the case of the low Mn end, the full test package has to be performed. As already mentioned the effects produced by the polymers normally decrease from the low to the high Mn, so if no toxicological/ecotoxicological effects are observed for the low Mn member no effects are expected in the case of the high Mn member. Therefore the technical dossier for the upper end of the family may be submitted without testing (a "nominal" notification) and the two dossiers cover the whole range (example 2). If, in contrast, certain effects are seen at the low Mn, these should be checked for at the upper end to see if they extend over the whole range (as in example 3) [if this is not
done, the dossiers cover only the polymer substance at each end of the range - example 4].

For the more usual situation of a "new" copolymer in which the Mn is "fixed" and the composition varies or alternatively the composition is "fixed" and the Mn varies, similar principles apply. Thus with the first such case, two technical dossiers are needed, one for each end of the range of compositions with the tests to be done usually on the polymer with most "new" monomer present (or if good reason, e.g. that the new monomer has been fully tested and found not to be classified but one of the other, EINECS-listed, monomers is, then the test should be done at that end of the range instead). As for the homopolymers case, if the tests on the chosen end of family are negative, no tests are required at the other end and the whole family is covered

(example 6). If some are positive, those tests should be repeated at the other end and if with the same result, again the whole family is covered. However in the case where toxicological/ecotoxicicological effects are seen at one end of the range and no effects in/at the other, additional technical dossiers or tests on other (intermediate) representative members are required to maintain the necessary standard of safety while at the same time preserving the simplified notification concept and avoiding over-classification. In the second case, tests are done at the low-Mn of the range and the family can extend upwards to any chosen Mn limit.

Either of the above procedures, 3.1 or 3.2 may also be used for those polymers for which a Reduced Test Package, see below, is acceptable (NB: where the Family Approach is used, the polymer at each end of the range must be of the RTP type if the omission of RTP-style test is to be allowed for the whole group. Otherwise one has the situation delineated in the next but one paragraph).

Some tests which are relevant for polymers with a high molecular weight (e.g. inhalation toxicity for polymer dusts) and some ecotoxicological tests (e.g. light-stability, long-term environmental extractivity) may be necessary post-notification for the respectively upper and lower end of the family.

In all cases, each "substance", as under 3.1 above, within the family which is marketed, will have to be briefly reported, but without the submission of a technical dossier, to the Competent Authorities.

4. Polymer for which a reduced test package is acceptable (RTP-polymers)

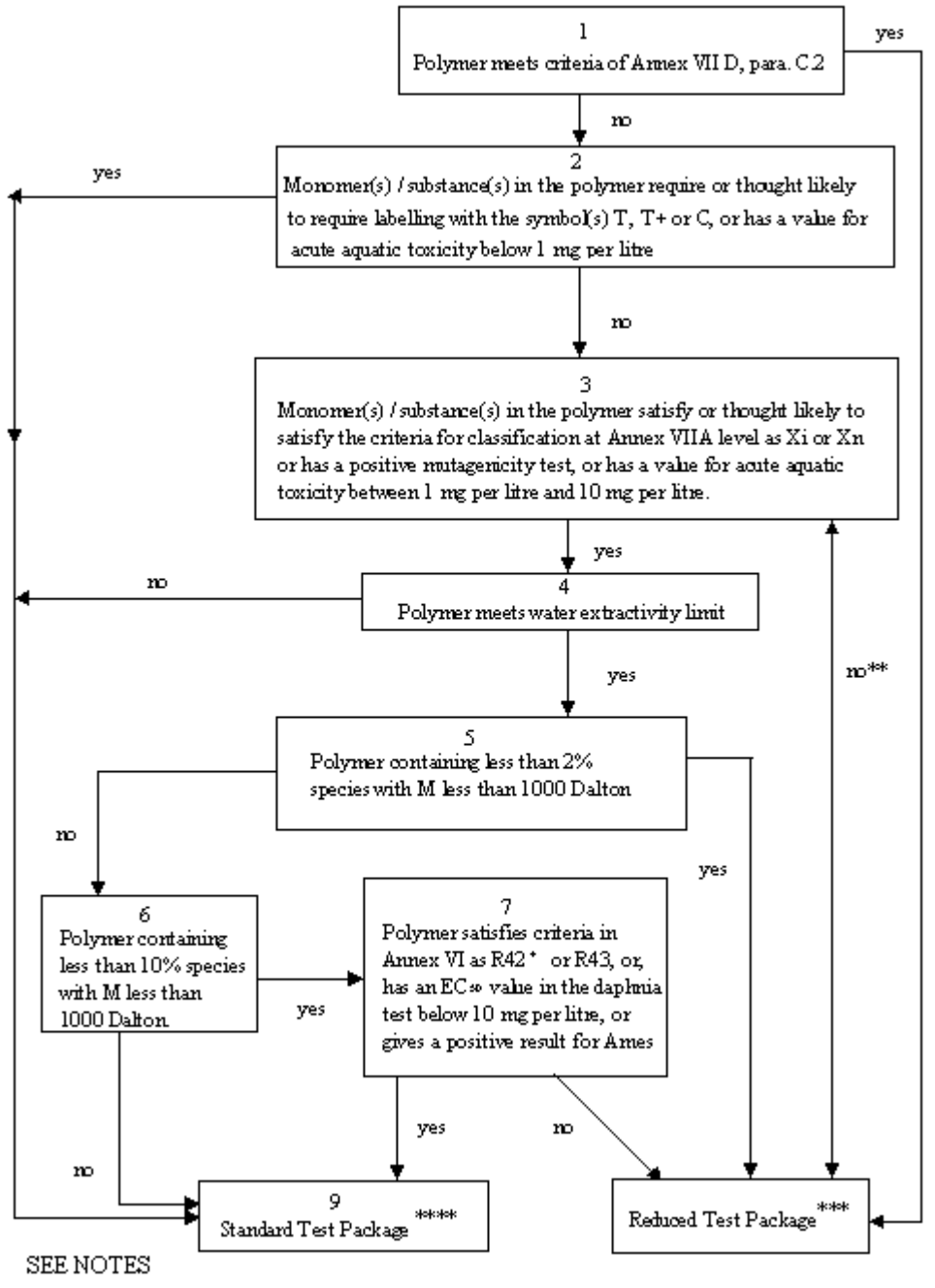
The fundamental idea of this concept is the assumption that non-bioavailable substances as indicated by the three criteria of high Mn, <1% of species with M<1000 and low water extractivity are not able to cause systemic effects which are toxicologically and/or ecotoxicologically relevant. However, this concept has been extended post-Annex VII D such that where a polymer breaks one of those criteria, it may still be possible to reach RTP or similar status by balancing the presumed, but still low, bioavailability that implies with a knowledge of the properties of the component monomers. These possibilities are indicated in the attached scheme, figure 1, but first the following section
gives in more detail the philosophy behind this concept for the original (Annex VII D) RTP polymer.

4.1 Criteria for the traditional Annex VII D RTP polymer

Polymers with a high Mn, low content of low molecular weight species as well as low solubility/extractivity in water are regarded as essentially non-bioavailable. Therefore, for polymers fulfilling the prescribed criteria, a reduced test package is acceptable.

A high molecular weight prevents, according to present knowledge, passage through biological membranes. As a guidance for this criterion a Mn> 10000 is used. Only when this value is not fulfilled, should polymers with Mn>1000 be considered (on a case by case basis). The up-take in aqueous solution is limited by the required low solubility/extractivity in water. A low proportion in the polymer with M<1000 represents a low toxicological/ecotoxicological activity of the polymer under the assumption that possible effects are due to low molecular weight species.

Figure 1. Route to the Reduced Test Package (RTP)*



Footnotes to notification scheme:

* RTP route cannot be applied to polymers containing certain reactive groups as specified in Annex 2 to this guidance document (XI/584/93 rev.3) nor to respirable/high Molecular weight polymeric dusts.

** Providing the Mn is > 1000 and it can be demonstrated (not necessarily by testing) that on simulated ingestion the polymer cleaves to the same or equivalent non-classified fragments.

*** The usual caveats as to possible post-notification testing (as in 93/105/EEC, C.2.1 items 4 and 5) apply.

**** Tests for STP may be omitted if all the monomers and substances in the polymer do not satisfy or are not thought likely to satisfy the criteria for classification in Annex VI to Directive 67/548/EEC for a particular end-point. The evidence may be that derived from reliable literature (e.g. RTECS, non-confidential IUCLID etc.) test data on close structural analogues, in-house worker protection tests, etc. The notifier has to provide the data.

\+ When test methods becomes available in Annex V this test will be required.

Explanation of the terms used in the boxes:

'monomers' describes the building blocks of the polymers.

'substances' is defined in Directive 67/548/EEC as amended by 92/32/EEC. It is included in this scheme as the chemical synthesis of polymers may include other building blocks than 'monomers', e.g. networking agents, chain terminators, initiators etc. which will be chemically bound in the final polymer.

'species' cover the individual molecules in the polymer (the 'individual molecule' is a specific polymer chain [e.g. the hexamer] within the over all polymer distribution).

'M' is the molecular weight of a individual molecule in the polymer.

'T+' is the symbol of 'very toxic' substance as laid down in the Directive 67/548/EEC. It includes the substances labelled with R39 'Danger of very serious irreversible effects'.

'T' is the symbol of 'toxic' substance as laid down in the Directive 67/548/EEC. It includes the substances which are carcinogenic and/or genotoxic.

'C' is the symbol of 'corrosive' substance as laid down in the Directive 67/548/EEC.

R42 and R43 are sensitizing substances by inhalation and skin routes respectively (test results).

Data requirements:

The minimum data set which should be available for the new monomers/substances is the data requirements laid down in Annex VII A of Directive 92/32/EEC. These data would be obtained by testing as the substance is new and thus supposedly not described in literature.

The data set required for the monomers/substances listed in EINECS should be data set equivalent to the requirements laid down in Annex VII A of Directive 92/32/EEC, in consultation with the Competent Authority. The evidence may be that derived from reliable literature (e.g. RTECS, non-confidential IUCLID etc.) test data on close structural analogues, in-house worker protection tests, etc.

The data expected for Box 7 are test results of testing on the actual polymer or read across from close analogues.

If the criteria are fulfilled, the hazard potential of the polymer should be limited, so that a reduced test package is acceptable.

Up to now, the concept is limited to non-readily-degradable polymers, since the effect of the degradation products cannot be estimated based on the composition of the polymer.

For non-readily-degradable polymers, that are placed on the Community market in quantities of < 1 t/a or total quantities of < 5 t, it is sufficient that the criteria of a high molecular weight and a low solubility/extractivity in water are fulfilled, because only a few tests are required in Annexes VII B and VII C for other chemicals and it would be an unreasonable expenditure to prove that the other criterion (i.e. < 1% with M < 1000) is fulfilled.

4.2 Test package for RTP-polymers

The reduced test package for RTP-polymers contains most of the physico-chemical tests in addition to the common declarations concerning the manufacturer, notifier, identity of the substance and information on the substance. However, the determination of the melting range can obviously be combined with the (polymer-specific) test for thermal stability by DTA or DSC, using e.g. OECD Test Guideline 113, though it should be noted that that cannot replace the test for explosive properties/autoflammability. However, for explosive properties the escape clause is very likely for polymers.

Most polymers for which the reduced test package is acceptable require in principle no toxicological and ecotoxicological tests at base-set level. If it seems likely that toxicity effects are due to low molecular weight components, classification (and the possible need for confirmatory testing) may be determined by application of the rules in the Preparations Directive.

The structural and physical characteristics of the polymer (reactive functional groups, bio-available metals, aerodynamic particle size) are also to be taken into account (described in detail in Annex 2), but if it can be scientifically justified the tests can be omitted.

A similar treatment to determine the need for ecotoxicological test should be possible once the Preparations Directive is modified adequately. Anionic and cationic charge densities as well as biotic and abiotic stability are also of concern.

In addition, tests for inhalation toxicity may be required, if a potential for such exposure exists, because dusty high molecular weight polymers may cause inhalation toxicity by overloading the clearance mechanism of the lung. Some ecotoxicologically relevant tests such as light-stability and long-term environmental extractivity may also be relevant. The reasons are already mentioned under 2.1.

4.3 Labelling of RTP polymers

Any polymer notified under one of the RTP procedures (see figure 1) must carry the "Caution-substance not yet fully tested" phrase in addition to any label required by testing.

5 Higher tonnage testing requirements

The tonnages follow the usual trigger levels for New Substances as laid down in Directive 92/32/EEC, the tests for polymers at higher tonnage triggers are as follows:

- For a polymer notified as a 'Standard Test Package Polymer' the standard testing program is to be followed, so this type of polymer notification will contain the end-points required for the Annex VII A and D, and appropriate Annex VIII tests. If it can be demonstrated that the ultimate buildings blocks are all 'negative' with regard to a particular end-point then testing for that end-point can be delayed until the 100 tonnes/annum (or 500 tonnes cumulative) level has been reached.

- For polymers following a 'Reduced Test Package' the testing is shifted so that the Annex VII A and D package is expected at 100 tonnes/annum level (and not at 1 tonne/annum). Then at the next tonnage trigger, 1000 tonnes, relevant tests from annex VIII (level one and two) are defined. For the RTP polymers following the Annex VIID, para 2 route it is expected that tests from Annex VIIA and VIII would not be relevant; however it should be evaluated on a case by case basis; when scientifically justified tests may be omitted.

To give an overview table 1 was compiled giving a schematic comparison of the testing requirements for the different substance classes at the tonnage levels. Annex 2 of this guidance note give further explanation to the toxicological and ecotoxicological testing of polymers subject to the reduced test package in Annex VII D para C.2.

TONNAGE	STP+ POLYMER	RTP POLYMER	ANY NEW SUBSTANCE
≥ 1 tonne/annum or ≥ 5 tonnes cumulative	Annex VIIA testing and some polymer specific tests	None (unless CA specifically requests)	Annex VIIA testing
≥ 10 tonnes/annum or ≥ 50 tonnes cumulative	Annex VIIA testing and some Annex VIII (level 1) at CA request	None (unless CA specifically requests)	Annex VIIA testing and some Annex VIII (level 1) at CA request
≥ 100 tonnes/annum or ≥ 500 tonnes cumulative	Annex VIIA testing and full Annex VIII (level 1)	Annex VIIA testing*	Annex VIIA testing and full Annex VIII (level 1)
≥ 1000 tonnes/annum or ≥ 5000 tonnes cumulative	Annex VIIA testing and full Annex VIII (level 2)	Annex VIIA testing and Annex VIII (level 1 and 2) depending on dialogue between CA and notifier*	Annex VIIA testing and full Annex VIII (level 2)

ANNEX 1. Examples

Examples are grouped by type of polymers

\+ If for a particular test end-points are negative for all monomers/substances in the polymer, then testing is not required on the polymer until 100 tonnes/annum or 500 tonnes cumulative threshold is reached.

* If omissions can be justified testing does not need to be performed (usual Annex VII preamble applies).

For the purposes of these examples the following abbreviations are used:

t+ : testing resulting in effects being seen

t- : testing resulting in no effects being seen

i : basic Mn etc. information on the substance but without tox/ecotox testing

rt+ : relevant tests with effects seen.

rt- : relevant tests no effects seen.

Firstly, there is the narrow-range type, a polymer "substance" (as defined under item 3.1), where a single notification dossier covers all the examples within that narrow-range of Mn and/or composition. Secondly, there are families, where there are two types of notification dossier - (a) one requiring the usual toxicological/ecotoxicological tests, except for RTP polymers, and carried out on the polymer with the lowest Mn or with composition highest in the (new) monomer or as indicated under item 3.2 para 5; (b) a "nominal" notification at the "other end" of the family which will either require (i) no testing to be done (if the tests done under the first notification were all "negative"), and signified by little i (information only) below; or (ii) where not all "negative", testing of those end points which were "positive" in the first notification (t+), and signified by the abbreviation rt+ or rt- below. Since the two individual dossiers represent a "substance", as defined under item 3.1, at each end of the family, the "validity" of that notification covers the substance actually tested but extending, for homopolymers for example, up to 3-fold its Mn whereas the two technical dossiers cover the whole range between the extremes of the family as indicated e.g. under example 2. Although "new" homopolymers will be rare, 3 examples (2-4) of the family approach for homopolymers are provided to illustrate the principle, which can be extended to "new" co-polymers.

HOMOPOLYMERS

Example 1, a polymer "substance"

mol. weight range proposed by the notifier	:	Mn = 500 - 1500
testing at	:	Mn = 500
validity of the technical dossier	:	Mn = 500 - 1500
validity of the notification	:	Mn - 500 - 1500

Graphic representation*

Technical dossier

```
 500              1500
II================II
```

t- or
t+

Notification

```
500              1500
I--------------------------I
```

* II extremes proposed by the notifier

I======I validity range of the technical dossier(s)

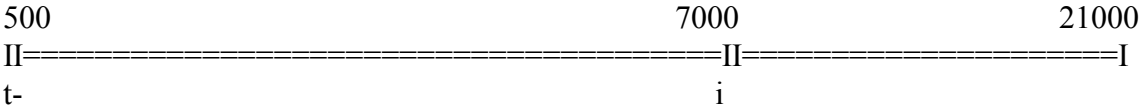
I----------I validity range of the notification(s)

Example 2, a family showing no tox/ecotox effects

family proposed by the notifier in the range from	:	Mn = 500 - 7000
testing for notification 1 (no effects seen) at	:	Mn =500
validity of notification 1	:	Mn = 500 - 1500
a "nominal notification" (see introduction) giving information on the substance, without toxicological and eco-toxicological testing, at	:	Mn = 7000
validity of nominal notification 2	:	Mn - 7000 - 21000
combined validity of the two dossiers for the family	:	Mn = 500 - 21000

Graphic representation of validity

Technical dossiers



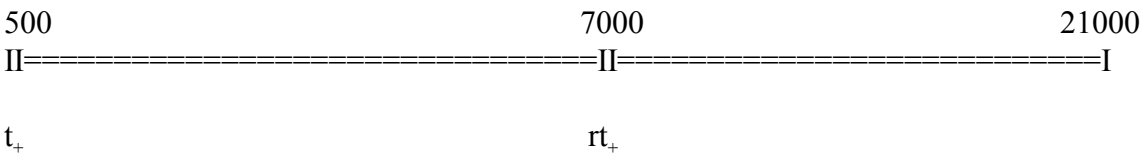
Notifications

Example 3, a family showing tox/ecotox effects at both ends of the range

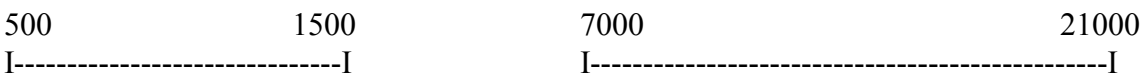
family proposed by the notifier in the range from	:	Mn = 500 - 7000
testing for notification 1 (with effects seen) at	:	Mn = 500
validity of notification 1	:	Mn = 500 - 15000
relevant tests (see Introduction), for notification 2 and the same effects seen, at	:	Mn = 7000
validity of notification 2	:	Mn = 7000 - 21000
combined validity of the two technical dossiers for the family	:	Mn = 500 - 21000

Graphic representation of validity

Technical dossiers



Notifications



Example 4, a family showing tox/ecotox effects at one end of the range but not the other

family proposed by the notifier in the range from	:	Mn 500 - 7000
testing for notification 1 (with effects seen) at	:	Mn = 500
validity of notification 1	:	Mn = 500 - 1500
relevant tests, and with no effects seen, at	:	Mn = 7000
validity of notification 2	:	Mn = 7000 - 21000
combined validity of technical dossiers 1 and 2 for the family	:	Mn = 500 - 1500 and 7000 - 21000

Graphic representation of validity

Technical dossiers

Notification

COPOLYMERS

Example 5, Copolymer A-B (Mn approximately constant and a narrow compositional range, a polymer substance).

Testing on the marketed polymer of composition 50% A - 50% B; a deviation of ± 10% absolute is acceptable. The variation in Mn acceptable will be a factor of 2.0. The notification (and technical dossier) is valid for the range from composition (1) to composition (2) and a molecular weight range from Mn to 2.0 Mn.

(1) 40% A - 60% B
(2) 60% A - 40% B

The notified polymer corresponds to one substance (see guidance, point 3.1), testing to be at the middle of the compositional range.

Example 6, Copolymer A-B (Mn approximately constant but a wide compositional range, family)

variations in composition: (1) 90% A - 10% B
(2) 25% A - 75% B.

Two technical dossiers required for copolymers with composition (1) and (2), with testing first, as indicated under item 3.2 para 5, at one end of the range and if no effects seen, information only at the other end but if effects then those (relevant) tests repeated there.

Validity of notifications as under example 5 (composition variation of ± 10%). Each dossier covers the tested composition ± 10% (as for example 5), but providing the same, or no, effects are seen at the two ends of the range, the two dossiers cover the whole family as for Example 2 and 3. M.Wt. variation allowed = 3-fold across the family.

Example 7, Copolymer A-B (composition approximately constant and a narrow M.Wt.variation, a polymer substance).

Testing on the marketed polymer with Mn = 1000 and composition 50% A - 50% B; a deviation of ± 3% absolute is acceptable.

The notification (and technical dossier) is valid for the range from composition (1) to composition (2) and a molecular weight range from Mn to 3 x Mn.

	Composition	Mn
(1)	47% A - 53% B	1000 up to 3000
(2)	53% A - 47% B	1000 up to 3000

The notified polymer corresponds to one substance

Example 8, a family of polymers in the form of a homologous series

This family consists of a group of molecules in which the polymer entity is the same and a homologous series of end-groups is attached; e.g.:

--------- C_8
---------- C_{10}
---------- C_{12}
---------- C_{14}
---------- C_{16}

The lowest (C_8) example of the homologous series would then have to be tested and notified and a nominal notification with basic physico-chemical data, and possibly some (eco)toxicological data, provided for the C_{16} example.

ANNEX 2.

DETERMINATION OF FURTHER TESTING (TOXICOLOGY, ECOTOXICOLOGY) OF POLYMERS FOR WHICH A REDUCED TEST PACKAGE IS ACCEPTABLE.
(POINTS 4 AND 5 OF SECTION C2.1 of Annex VIID)

1. Introduction

In general toxicological, ecotoxicological tests are to be performed if required by the competent authority on a case by case basis. The tests required depend on structural and physical characteristics. They do not delay acceptance of the notification but must be performed within a reasonable timescale.

2. Toxicology

The following parameters should be considered when making a decision on the necessity of toxicological tests:

2.1 Presence of reactive functional groups

Polymers containing reactive functional groups may be capable of reacting with tissues or with other chemical constituents, and reactive groups may cause sufficient irritation to disrupt normal cell membrane barriers and therefore facilitate penetration. If those groups are present in the polymer, the higher possibility of presence of these effects should be taken into account when designing the test package. The kind of functional groups which may induce such effects are exemplified in the following:

acid halides; acid anhydrides; aldehydes; hemiacetals; methylolamides,-amines, or -ureas; alkoxysilanes (> C2); allylethers; conjugated olefines; cyanates; epoxides; imines; substances with unsubstituted ortho or para positions to phenolic hydroxyl. Groups of more concern are pendant acrylates and methacrylates; aziridines; carbodiimides; halosilanes; hydrosilanes; hydrazines; isocyanates; isothiocyanates; alpha or beta lactones; methoxy or ethoxy silanes; vinysulfones or analogous compounds.

2.2 Presence of bioavailable metals, that are part of the polymer structure

The toxicological effects due to bioavailable metals should be taken into consideration when deciding on further toxicological testing of RTP-polymers.

2.3 Aerodynamic particle size

A (solid) polymer with particles of a respirable size may cause inhalation toxicity. If such an exposure potential exists, test on inhalation toxicity should be considered.

2.4 Low molecular weight content

The following procedural rules for the determination of further testing are based on the fact that a polymer is normally a mixture comprising a high molecular weight portion, a low molecular

weight portion (monomers, oligomers; M < 1000), impurities and essential additives. Possible systemic effects can, in principle, be due to low molecular weight components.

2.4.1 Effects of the low molecular weight components are sufficiently known

If the effects of the low molecular weight components are sufficiently known the polymer should be classified in accordance with Article 4(1) of Directive 67/548/EEC. For this purpose additives should be treated as impurities.

2.4.2 Effects of the low molecular weight components are not sufficiently known

If the effects of the monomer, oligomers, impurities and/or additives are not sufficiently known (e.g. the chemicals are not included in Annex I of the Directive), they should be estimated (low molecular weight species with M < 1000 are considered to have the same properties as the monomer). In the case of untested effects a worst case assumption is made (that the effects are present). The default concentration limits of the Preparations Directive (88/379/EEC) are then applied to the estimated effects. The concentration limits have to be modified, if necessary, by SAR to a substance-specific lower value.

3. Ecotoxicology

The parameters mentioned in connection with toxicological tests under 2.1 and 2.2 (reactive functional groups, bioavailable metals) and anionic charge density may be also relevant for the decision on the necessity of ecotoxicological tests.

In addition, another factor is of relevance:

3.1 Cationic charge density

Cationic, water-soluble or dispersible polymers are available when in the aquatic environment and may therefore be able to cause toxicity to aquatic organisms. To estimate the possible effects of the polymer, the cationic charge density should be calculated on the basis of the polymer composition. Polymers with a cationic functional group-equivalent weight[(2)] of 5000 or greater are regarded as having not sufficient cationic characteristics to cause environmental effects. Consequently this value should be used as a guidance. All amines (primary, secondary, tertiary amine and quaternary ammonium), phosphonium and sulfonium should be included in the calculation. Nitrogen from amides, aromatic amines, aromatic triazines and melamines also need to be considered.

4. Overall assessment

The overall effects of a polymer are to be determined by the estimated effects of the low molecular weight components. If toxicological/ecotoxicicological effects appear likely, relevant tests have to be carried out. Considerations about structural and physical characteristics of the polymer (e.g. reactive functional groups, bioavailable metals, aerodynamic particle size, anionic and cationic charge density) are also to be taken into account. If it can be scientifically justified the tests can be omitted.

[2] Equivalent weight means the ratio of the Mn to the number of cationic functional groups.