LOW REGULATORY CONCERN CHEMICAL (LRCC)

Discussion Paper No. 6

LOW REGULATORY CONCERN POLYMERS

1. PURPOSE

This discussion paper seeks comment on proposals to extend the number of polymers which qualify for reduced notification and assessment requirements via the consideration of low regulatory concern.

2. BACKGROUND

In the Final Report and Recommendations for the Low Regulatory Concern Chemicals (LRCC) Reform Initiative (June 2003) and the subsequent Implementation Strategy (July 2003), Recommendation 4.3 stated for low regulatory concern polymers (LRCPs):

> *Introduce audited self-assessment for low regulatory concern polymers (i.e. polymers which do not meet the existing PLC criteria). New NICNAS criteria will need to be developed with industry and community involvement.*

Preliminary work by LRCC technical working groups defined LRCPs as those polymers which do not meet the PLC criteria but, for one reason or another, do not warrant a complete risk assessment. LRCPs would include other classes of low hazard polymers, analogues and polymers assessed under other regulatory schemes. Typical LRCPs could therefore include the following:

- Polymers of certain classes which are of low hazard;
- Polymers chemically similar to polymers already assessed by NICNAS;
- Consolidated notification, where more than one polymer can be notified and assessed together; and
- Polymers assessed by other regulatory schemes.

3. PROPOSAL

It is proposed to implement regulations and guidelines to enable the introduction of polymers identified as LRCPs. These proposals apply to all certificate categories and are listed below.

3.1 Polymers chemically similar to polymers already assessed by NICNAS

(a) If one monomer less

The reactive functional groups in a polymer are derived from the reactive functional groups of the component monomers and other reactants. In the risk assessment of polymers, the characteristics of these reactive functional groups play a large part in determining the polymer's health and environmental effects. For this reason, the type and content of reactive functional groups are key criteria in determining whether a polymer is a polymer of low concern.

For a polymer assessed by NICNAS, the contribution by the functional groups of the component monomers and other reactants to the polymer's health and environmental effects is taken into account in the hazard assessment. Consequently, for a new polymer with one monomer less than an assessed polymer, the health and environmental effects are largely known and the hazard assessment effectively completed.

It is therefore proposed that, for a polymer with one monomer less than a polymer already assessed, a reduced fee of 40% will apply. If the use is similar, a further 20% reduction is proposed.

It is proposed that this approach and reduction in fees be available to all certificate categories, including PLCs.

(b) If similar monomer substituted

Additionally, this proposal applies for a new polymer containing a reactant similar to that in a polymer already assessed, provided that the substituted reactant meets the *Guidelines for Acceptable Analogues* prepared as a separate discussion paper. For example, if propanediol is replaced by butanediol as a monomer in a polymer, then the new polymer would be regarded as an acceptable analogue.

(c) Polymer identical to assessed polymer

In some cases, a polymer may be manufactured by different reaction pathways and, in some cases, using different reactants. This can lead to the identification and naming of a particular polymer in more than way, with different CAS registry numbers, as polymers are usually identified and named in accordance with the names of the reactants used to manufacture the polymer.

It is proposed that, in these circumstances, a similar approach to (a) and (b) above will apply, with similar reductions in fees.

3.2 Consolidated notification, where more than one polymer can be notified and assessed together ('family approach')

In some cases, polymer analogues are developed together, leading to marketing and notification within similar timeframes. It is proposed that where analogues are notified together, as a family, and that one assessment suffices for the group of analogues (family), an administrative fee only will apply for subsequent members of the family. An example is the notification of three salts of a polymer, where one

assessment would suffice for the group of polymers. Consideration as suitable analogues for this proposal will be in accordance with the *Guidelines for Acceptable Analogues* prepared as a separate discussion paper (No. 4).

3.3 Polymers assessed by other regulatory schemes

Under the Act, NICNAS is required to complete a full risk assessment for new chemicals and polymers. If the chemical or polymer has been previously assessed by a competent overseas regulatory authority formally declared an approved foreign scheme under section 43 of the Act, the previous risk assessment can be taken into account. In this case, a reduced fee applies, however, no foreign scheme has been approved to date, although it is proposed to recognise the Canadian notification and assessment scheme in the near future.

Transitional regulatory arrangements have been in place for some years which allow the Director to remit fees at up to 40% on provision of an assessment report from a recognised foreign scheme. For polymers notified as PLCs in Australia, a free Early Introduction Permit is also available under the transitional arrangements for polymers assessed in Canada. However, these provisions have not applied to other national regulatory schemes or international assessment schemes.

It is proposed that, for polymers assessed by any competent authority, both national and international, and an assessment is available, that reduced fees apply, namely, 40% for the hazard assessment and an additional 20% for a similar use, where exposures are equivalent.

3.5 Low hazardous classes of polymer

Low hazardous criteria for notification and assessment purposes have been proposed for polymers and are included in the separate discussion paper on low hazardous criteria (Discussion Paper No. 1). For convenience, the criteria are as follows:

> *For low-hazardous polymers with number-average molecular-weight of 1000 or less, it is proposed that the criteria developed and proposed for chemicals be adopted (criteria in separate discussion paper on low hazardous criteria for notification and assessment purposes).*
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> *For low-hazardous polymers with number-average molecular-weight greater than 1000, it is proposed that the polymer has:*
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> - *less than 10% by mass of molecules with molecular weight that is less than 500; and*
> - *less than 25% by mass of molecules with molecular weight that is less than 1000; and*
> - *low charge density, as defined in Regulation 4C.*
>
> *In both situations, polymers shown to not meet the definition of 'a hazardous chemical' would also be accepted under this proposal.*

Polymers classified as NOHSC Type I ingredients or which are persistent or bioaccumulative would not be eligible for consideration as low hazard polymers.

In addition, NICNAS is working with the US and Canada and through the OECD New Chemicals Task Force to identify additional specific classes of polymer which can be accepted as 'low regulatory concern'.

3.6 Self-assessment

It is proposed that the self-assessment option for low regulatory concern polymers be deferred until some assessment experience is developed with these new notification categories.

4. SAFEGUARDS

It is intended that all polymers will undergo some level of assessment and therefore provide a safeguard to workers, the public and the environment. Concerns which arise during the prescreening phase can be addressed and, if necessary, additional data requested and/or additional risk management controls applied. For example, where the monomer ratio in a new polymer may be increased in comparison to a previously assessed polymer, leading to a higher concentration of a particular reactive functional group, these concerns can be addressed during the assessment process.

5. INFORMATION REQUIRED IN APPLICATION

The proposals outlined above for low regulatory concern polymers are intended to apply to all certificate categories. Therefore the data requirements will depend on the certificate category applicable, that is, Standard Notification, Limited Notification or Polymer of Low Concern. Where the hazard assessment is already available, e.g. from an overseas scheme, then separate data need not be submitted.

5.1 Form of Application

An electronic template will be available on the website for applications.