Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development

27-Jan-2009

English - Or. English

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

DATA ANALYSIS OF THE IDENTIFICATION OF CORRELATIONS BETWEEN POLYMER CHARACTERISTICS AND POTENTIAL FOR HEALTH OR ECOTOXICOLOGICAL CONCERN

JT03258707

ENV/JM/MONO(2009)1
Unclassified

English - Or. English

OECD Environment, Health and Safety Publications

DATA ANALYSIS OF THE IDENTIFICATION OF CORRELATIONS BETWEEN POLYMER CHARACTERISTICS AND POTENTIAL FOR HEALTH OR ECOTOXICOLOGICAL CONCERN[1]

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among UNEP, ILO, FAO, WHO, UNIDO, UNITAR and OECD

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 2009

[1] In this report, the term "concern" is used, but it is noted that the analyses in this report are based on the intrinsic properties of the polymers and did not consider exposure or risk.

Other OECD publications on New Chemicals:

Guidance on Definitions of Key Terms for New Chemical Notification [ENV/JM/MONO(2007)13] (2007)

Pilot Phase of the OECD Parallel Process for the Notification of New Chemicals [ENV/JM/MONO(2006)12] (2006)

About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 30 industrialised countries in North America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

The Environment, Health and Safety Division publishes free-of-charge documents in ten different series: **Testing and Assessment**; **Good Laboratory Practice and Compliance Monitoring**; **Pesticides and Biocides**; **Risk Management**; **Harmonisation of Regulatory Oversight in Biotechnology**; **Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; Emission Scenario Documents; and the Safety of Manufactured Nanomaterials.** More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (http://www.oecd.org/ehs/).

This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organizations.

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The participating organisations are FAO, ILO, OECD, UNEP, UNIDO, UNITAR and WHO. The World Bank and UNDP are observers. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

OECD Environment Directorate,
Environment, Health and Safety Division

2 rue André-Pascal
75775 Paris Cedex 16
France

Fax: (33-1) 44 30 61 80

E-mail: ehscont@oecd.org

FOREWORD

In March 2007, the OECD Task Force on New Chemicals Notification and Assessment organised an Expert Group Meeting on polymers, held in Tokyo, Japan. The meeting was organised to (i) share information on national legislative schemes; (ii) review commonalities and differences in criteria, approaches and methodologies with a focus on low concern polymers; (iii) consider the merits of various approaches; and (iv) investigate the potential for a common approach. At the meeting, the Expert Group recommended that a scientific examination of the *Polymer of Low Concern* concept be performed, through an analysis of polymer data submitted by OECD regulatory authorities. This work was carried out in 2007 and 2008, and Australia served as the lead country for the analysis.

The main purpose of the following analysis was to identify correlations between polymer characteristics and potential for health or ecotoxicological concern.

DATA ANALYSIS OF THE IDENTIFICATION OF CORRELATIONS BETWEEN POLYMER CHARACTERISTICS AND POTENTIAL FOR HEALTH OR ECOTOXICOLOGICAL CONCERN[2]

1 Table of contents

[2] In this report, the term "concern" is used, but it is noted that the analyses in this report are based on the intrinsic properties of the polymers and did not consider exposure or risk.

2 Executive Summary

In March 2007, the OECD Task Force on New Chemicals Notification and Assessment organised an Expert Group Meeting on polymers, held in Tokyo, Japan. At this meeting, the Expert Group agreed to carry out a preliminary analysis of data on polymers with a view to share experiences and provide evidence for countries to reconsider their rule regarding identification of Polymers of Low Concern (PLCs). Data for 205 polymers were collated from Australia, Canada, Japan, Korea and US. Countries classified the polymers under two categories (PLCs and non-PLCs) using the US EPA criteria. The analysis was aimed at identifying correlations between polymer characteristics and potential for health or ecotoxicological concern[3].

Data of variable quality were collected. Several health effects were reported for polymers, and it was not possible to critically evaluate the quality of this data based on what was available. Also, examination of specific effects was not possible, so a conservative approach - grouping polymers into low concern and potential concern groups - was used in this initial analysis.

Polymers that were considered to be PLCs showed generally low concern for health or ecotoxicological effects, although some effects of potential health concern were reported. **Amongst the polymers that met the PLC criteria, 87.8% showed low health concern and/or low ecotoxicological concern**. This value represents the outcome of this initial analysis, given the level of confidence in the available data. It is noteworthy that such a large proportion of PLCs were clearly of low health concern despite the use of conservative assumptions.

It is likely that a higher level of confidence could be achieved with improved data quality and analytical techniques.

One of the most striking findings related to the **number-average molecular weight** (Mn) of a polymer; the lower the Mn, the higher the potential for health or ecotoxicological concern. Similar results were obtained when the contents of low molecular weight, **oligomeric species** were investigated – the higher the content, the more likely a polymer was to display concern.

Trends were not clearly observed between **polymer class** and any observed toxicity, but many classes were each represented by only a few polymers. No potential for health concern was observed amongst the polyesters of the dataset. With additional data it might be possible to draw some further conclusions.

Reactive functional groups were more often seen in potential health and ecotoxicological concern polymers than amongst the low health concern polymers, but the level of data available was insufficient to confidently analyse any specific reactive functional groups. No confident trends were observed between the **functional group equivalent weight** (FGEW) of

[3] In this report, the term "concern" is used, but it is noted that the analyses in this report are based on the intrinsic properties of the polymers and did not consider exposure or risk.

a polymer and its potential for concern. However, there was some suggestion that higher concern polymers had lower FGEWs than low concern polymers.

A higher proportion of polymers with intermediate **water solubility** values (10-10000 mg/L) displayed potential health concern. Polymers with water solubilities <10 mg/L showed generally low health concern. No correlation could be drawn between ecotoxicological concern and water solubility.

Overall, this initial analysis has provided scientific evidence that builds confidence in the PLC criteria (where sufficient data were available). The instances where potential concern was observed for PLCs do not invalidate this conclusion.

The hypothesis that polymers meeting the PLC criteria are likely to have insignificant human health or environmental impacts is thus supported, and suggests that regulatory requirements might be reduced for these polymers. From the knowledge gained during this analysis, future work should increase confidence through the collection of stronger data and further analysis.

3 The purpose of this report

The primary aim of this report is to present the initial analysis that has been conducted on the collected polymer data. The shortcomings of both the data and the analysis will be presented, and possibilities for future work discussed.

4 Background

4.1 PLCs and the OECD Polymer Working Group

In March 2007, the OECD Task Force on New Chemicals Notification and Assessment organised an Expert Group Meeting on polymers, held in Tokyo, Japan. The objective of the meeting was (i) to share information on national legislative schemes, (ii) to review commonalities and differences in criteria, approaches and methodologies with a focus on low concern polymers, (iii) to consider the merits of various approaches and (iv) to investigate the potential for a common approach.

It was noted at the meeting that the OECD definition of a polymer has been widely adopted and incorporated in the regulation of many governments. However, this harmonization has not been reached for the criteria used to identify PLC. It was also noted that except in the EU system, all other jurisdictions integrate the concept of polymers of low concern into their regulation. The general acceptance of the PLC concept then constituted the basis for the discussions during the meeting. To strengthen this basis, the group discussed and agreed on a definition of a PLC.The proposed definition of a PLC is the following:

> *"Polymers of low concern are those deemed to have insignificant environmental and human health impacts. Therefore, these polymers should have reduced regulatory requirements."*

The Expert Group proposed to perform a scientific examination of the PLC concept, through an analysis of polymer data submitted by the regulatory authorities of member nations. Australia was to be the lead in this process.

Data for polymers that had available toxicological and/or ecotoxicological data was to be provided by Australia, Canada, Japan, Korea, and the USA. Polymer data were provided to Australia (NICNAS) by mid-June 2007. NICNAS has collated and performed an analysis of this data, culminating in this report. This work has been discussed at Polymer Working Group teleconferences throughout the data collection and during the analysis.

4.2 The PLC criteria

Member nations' agencies differ in the criteria that are used to establish a polymer as a PLC. However, some similarities can be observed, in those parameters that might predict the ability of a polymer (or its components) to cross biological membranes.

The most common of these is the **number-average molecular weight (Mn)**. An Mn of ≥1000 Da is a generally accepted Mn range for a PLC.

Directly related to Mn is the content of **low molecular weight, oligomeric species** (i.e., <1000 Da and/or <500 Da species). However, different jurisdictions differ widely on the level of oligomeric species that are permitted in the PLC category. Some nations specify limits for just <1000 Da content, whereas others regulate both <1000 Da and <500 Da. For example:

- The USA, Canada and Australia specify weight % oligomer content cut-offs on the basis of the Mn of the polymer. For a polymer of 1000 Da < Mn < 10000 Da, a limit of <25% applies to polymer oligomer content of <1000 Da, and <10% of <500 Da species is permitted. For a polymer of Mn >10000 Da, an oligomer content of <5% of <1000 Da and <2% of <500 Da species is permitted.

- Japan has a single weight % <1000 Da oligomer content cut-off of <1%, based on data showing toxicity for polymers containing of greater levels of oligomer content.

In addition, a common criterion is the presence or absence of specific **reactive functional groups (RFGs)** in the polymer. These are functional groups that are known to be associated with toxicity of polymers, and include cationic species that are known to result in aquatic environmental toxicity. Limits on RFG content can be defined in terms of the **Functional Group Equivalent Weight (FGEW)**, a measure of the "dilution" of an RFG amongst the polymer's other components. RFGs or the FGEW are not universally considered for establishing a PLC.

Other criteria that are used by some jurisdictions to define a PLC include the polymer's stability, solubility (in water and other solvents), chemical class (henceforth referred to as polymer class), residual monomer content and human health hazard classification.

5 Data collection and analytical method

5.1 Data template

Polymer data were provided using a standardised template that also reported conclusions on health/environmental effects where these were available. Polymer data on the following parameters were collected:

> *Identifier, Polymer Class, Functional Groups of Concern, FGEW, Mn, wt% <1000 Da, wt% <500 Da, Unreacted monomer excluded (Y/N), Solubility/Extractability, Health toxicity, and Ecotoxicity/Biodegradation Studies.*

Additionally, clarification was sought as to whether or not each polymer fit the US EPA's PLC criteria (http://edocket.access.gpo.gov/cfr_2003/julqtr/40cfr723.250.htm).

A significant quantity of data was received, for a total of 150 polymers. A spreadsheet containing collated data and some preliminary descriptive analysis was circulated to the group on 25 June 2007. The dataset was found to include polymers that were not considered to be PLCs, but these were included for the purposes of identifying trends and validating their exclusion on the basis of their properties.

Following the circulation of the first draft version of this report, additional polymer data was sought from the participating agencies. Data for an additional 55 polymers was received from Canada and Japan, enabling several additional analyses to be performed.

5.2 Refinement of data

Interpretation of data and assumptions

Polymer data was provided in a highly variable fashion, and no verification of parameters was possible. The polymer data had to be refined into a consistent and standardised format. Significantly, this process involved considerable interpretation of the data, and often this required the use of conservative assumptions.

Where non-numerical data, data ranges or limit values were present, these values were simplified into a single value (as described in more detail below). Occasionally, data described in text form had to be converted into a numerical value for the purposes of achieving a complete data set for analysis. This was carried out arbitrarily, as described below for each data point. In other places, where assumptions based on the PLC criteria seemed reasonable to apply to the data, data gaps were filled arbitrarily.

Where a limit value or an approximate value (e.g. '<123' or 'about 123') was used, the value was used (e.g. 123). Without this, such data would not be able to be represented graphically.

For some polymers, some assumptions had to be made about whether a polymer was a **PLC or non-PLC** based on the criteria of the US EPA. Confirmation of these classifications was sought from the jurisdictions that provided the data for each polymer. At the time of writing

of this report, 14 polymers had to be assigned as PLCs or non-PLCs solely on the limited data available.

Polymer classes were simplified as much as was possible, while considering the limitations of the available data. Polymer class data was simplified into 13 "numerical classes":

1. Polyesters,
2. Polyolefins
3. Polyacrylates
4. Polyethers
5. Polyurethanes
6. Polyamides
7. Polyimides
8. Polysaccharides
9. Polyvinyl
10. Siloxanes and silicones
11. Other
12. Mixed
13. Epoxy resins

Many polymers appeared to belong to two or more classes, and these were assigned to the "mixed" class. Polymers that did not fit into the main categories, or where some doubt existed as to which class applied (e.g. 'other') were placed into the "other" class.

Reactive functional groups (RFGs) were simplified by describing them as "None" or by a single, uniform name. Where no data was present, the polymer was considered as "Not determined", and these polymers were not used for any RFG analysis. Polymers with "ill-defined" RFGs were considered as RFGs in the absence of better data. The **"RFG rating"** was used in analyses: 0 = Not determined, 1 = contains no RFGs, 2 = contains any RFG.

FGEW threshold values of eg '<5000' were listed as just '5000'. Where it was stated that 'No FGEW calculation was required' or 'N/A', this was substituted with '0'. Where a polymer had two FGEW values (i.e. two RFGs), the lower value was selected. Where no data was present, or where the polymer had no RFGs, the value '0' was inserted unless it was clear that the polymer was unlikely to have such an FGEW (e.g. non-PLCs).

The upper limit of any data ranges was chosen for **oligomer content**. Where values were stated as 'not detected', this was substituted with '0'.

For **number-average molecular weight** (Mn), the lower limit of any data ranges was chosen.

Of the solubility data, only **water solubility/extractability** data were retained, as there were insufficient data on any other solvents for analysis. All data were converted to equivalent values in mg/L. Water-miscible or "soluble" polymers have been represented with a water solubility of 1000000 mg/L ($1x10^6$ mg/L; an arbitrary value). Polymers with "negligible" water solubility, or those described as "hydrophobic" have been represented with a water

solubility of 0.000001 mg/L ($1x10^{-6}$ mg/L; assigned arbitrarily). The upper limit of water solubility ranges was chosen. Data for water-dispersible or emulsion-forming polymers was disregarded, unless some other indication of their true water solubility was provided. Likewise, water solubility data provided in 'mg C/L' or '% C w/w' could not be converted into an aqueous polymer concentration in mg/L, and were excluded.

In order to simplify the toxicological data to achieve the largest dataset possible, the available data for health end-points were grouped into a "**health concern rating**". This was achieved by categorising the outcomes of any and all toxicological testing for a given polymer into one of three groups (based on the data available):

1. No toxicity data

2. "Low health concern" - these have:
   - None or minor observed effects
   - Low acute oral, inhalation or dermal toxicity (i.e. LD_{50} >1000 mg/kg)
   - Mild/slight irritation to eye or skin

3. "Potential health concern" - i.e. those that have:
   - Moderate or high acute oral, inhalation or dermal toxicity (i.e. LD_{50} ≤1000 mg/kg)
   - Greater than mild eye or skin irritation
   - Positive skin sensitisation (including 'limited evidence')
   - Any positive mutagenicity or genotoxicity test (*in vivo* or *in vitro*)
   - NOEL or NOAEL ≤750 mg/kg/day
   - Any other positive test result

Note that the concern ratings used in this report to describe the potential of a polymer to exhibit health effects do not imply any measure of potency or probability that the polymer presents a hazard. These terms have been used merely to refer to the above groups for the purposes of analysis. That is, a term such as "potential health concern" might describe a wide range of possible effects when used to describe a polymer.

If a polymer was placed into the potential health concern group, the causative result was noted (e.g. "Moderate eye irritant" or "LD_{50}=500 mg/kg").

Ecotoxicological data were categorised for Fish, *Daphnia* and Algae only, according to the following rating scale:

0. No data
1. "Low ecotoxicological concern" (EC_{50} or LC_{50} >100 mg/L)
2. "Moderate ecotoxicological concern" (EC_{50} or LC_{50} = 1-100 mg/L)
3. "High ecotoxicological concern" (EC_{50} or LC_{50} <1 mg/L)

Where a single polymer had multiple test results for similar species of one category of aquatic life (e.g. fish or *Daphnia*), the highest concern result (i.e. lowest concentration or lethal dose) was chosen to place it in the group. Finally, the **maximum ecotoxicological concern rating**,

i.e. the highest concern rating for that polymer for toxicity to any species, was determined for each polymer (to enlarge the ecotoxicological dataset available for a single analysis).

5.3 Method of analysis

The refined data were analysed using Microsoft Excel 2003. Statistical analysis was performed using Student's *t*-test, assuming equal variance and two-tailed distribution. Further descriptions of specific analyses are provided in the legend to each figure (where appropriate).

It should be noted that in several analyses, polymers with different concern ratings (health or ecotoxicological) were directly compared. Where a specific polymer parameter was scrutinised, it was considered that trends of higher polymer toxicity would be observed as a greater proportion of polymers with higher concern ratings. Conversely, a parameter was considered less important for correlating with polymer toxicity where the incidences of polymers with higher concern ratings were equivalent to the incidences of low concern polymers, or where low concern polymers predominated.

6 Results and discussion

6.1 Description of the polymer dataset

Initially, a descriptive analysis was performed to determine the strengths and/or weaknesses of the dataset to support further analysis. Out of the 205 polymers submitted, 139 polymers were PLCs according to the US EPA's PLC criteria, and 66 polymers were non-PLCs.

An analysis of the dataset by **polymer class** showed that a range of chemistries is represented in the dataset (Figure 1). Compared with the other polymer classes, there was little data available for five classes: polyamides, polyimides, polysaccharides, polyvinyls and epoxy resins. In addition, several polymers were grouped into the "mixed" or "other" classes due to their uncertain or unique chemistries, as these may not have sufficient numbers to add significantly to the data on their own. Conclusions cannot be made about any observed trends for these two groups of polymers.

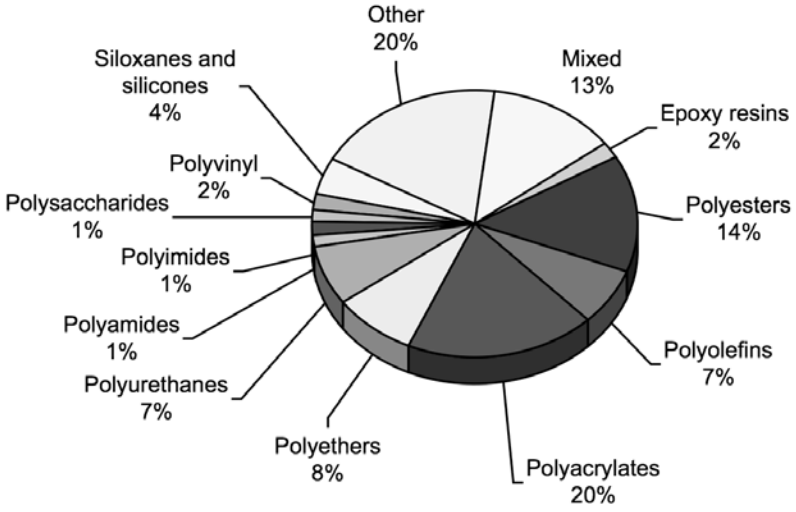


Figure 1.*A breakdown of the polymer data by polymer class.*

In addition, polymers considered to not be PLCs were distributed amongst the different polymer classes (Figure 2).

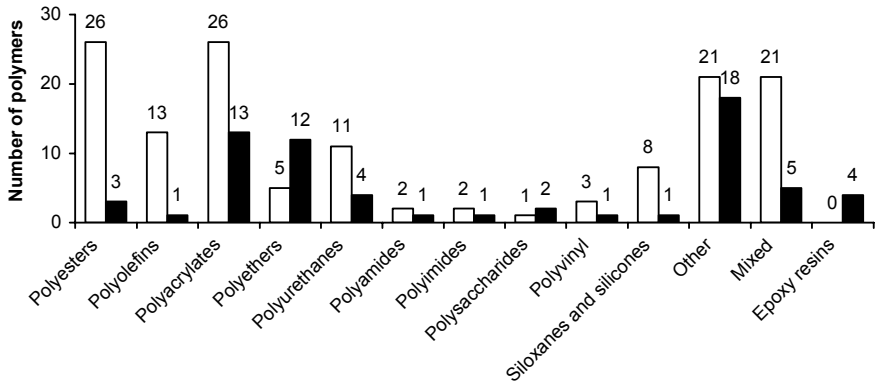


Figure 2.*The number of PLCs and non-PLCs in each polymer class. PLCs are shown in white and non-PLCs are shown in black.*

RFGs were found in only 32% of polymers (66 in total). The incidences of specific RFGs were as follows: amino (26), epoxide (7), isocyanate (3), anhydride (4), alkoxysilane (1), sulfonate (1), (ortho to a) phenolic hydroxyl (8), allyl ether (1), pendant acrylate (5), cationic (other) (2), fluorinated (6), and ill-defined (4). With the exception of perhaps the amino group, the RFG dataset showed a poor representation of most RFGs. **FGEW** values were provided for 53 polymers with RFGs.

A broad range of **Mn** values were present in the dataset, as shown in Figure 3. The average Mn was 76118 Da, and the median Mn of the dataset was 4000 Da. As all of the polymer data provided contained data on Mn, this parameter was considered a good candidate for analysis.

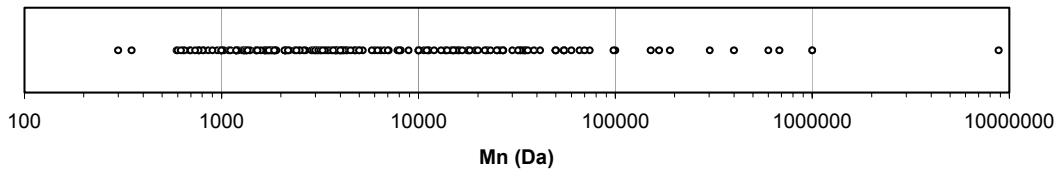


Figure 3.*The distribution of Mn values in the dataset.*

The median weight % of <1000 Da **oligomeric content** in the dataset was 3.23% (range 0-100%, n=201), and that of <500 Da content was 1.00% (range 0-50%, n=179). Both of these parameters held sufficient data for carrying out further analysis.

Unreacted monomer(s) were present in 147 of the polymers (71.7%), 41 did not contain any residual monomer (20%), and the presence or absence of monomer was uncertain in 17 polymers (8.3%). However, while the majority of polymers contained one or more unreacted monomer species, the identity, concentration and toxicity of these were unknown. These data were considered to be poor for carrying out further analyses, and was not examined further.

Water solubility/extractability data were provided for 85 polymers (41.5% of the total data), and the median water solubility of the dataset was 483 mg/L. The distribution of the water solubility is shown in Figure 4, and this figure demonstrates that the majority of polymers in the dataset have a water solubility of >1 mg/L (64 polymers, 75.3% of those polymers with available water solubility data).

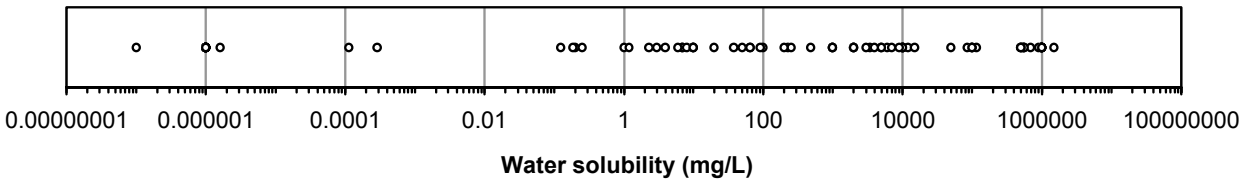


Figure 4.*The distribution of water solubility/extractability data*

Of the 205 polymers, 109 (53%) were of low health concern (Figure 5). Toxicological data that is suggestive of potential health concern was found for 33 polymers (16%), whereas 63 polymers (31%) had no health effect data available. This dataset was considered to be robust, as a total of 142 polymers had toxicological data available.

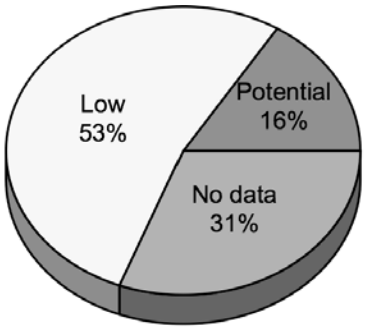


Figure 5.*The polymer dataset by health concern rating.*

The health concern data was then divided amongst the PLCs (139 polymers) and amongst those polymers that were deemed to be non-PLCs (66 polymers), shown in Figure 6. It is apparent that a greater proportion of non-PLCs had data suggesting potential health concern (Figure 6B) than do PLCs (Figure 6A). However, it should be noted that 17 polymers that were PLCs were categorised as potential health concern.

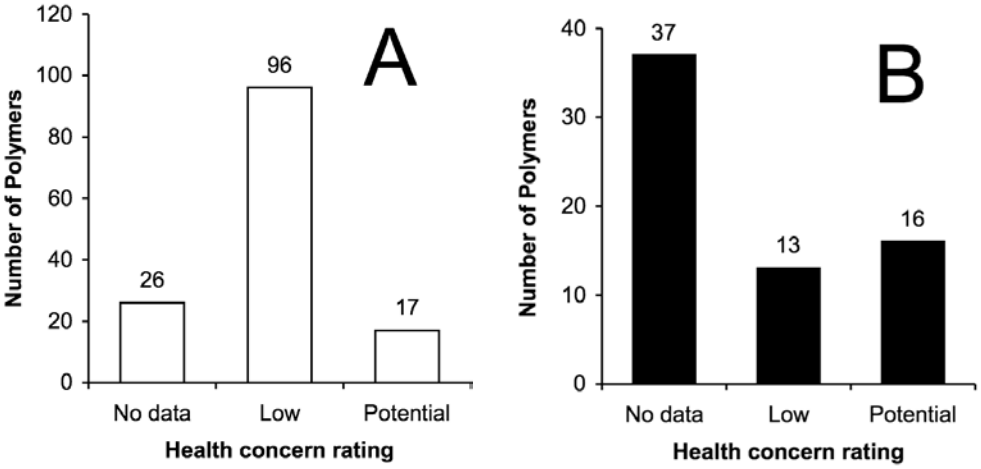


Figure 6.*The relationship between PLC status and health concern rating, for (A) PLCs and (B) non-PLCs.*

The polymers that exhibited specific potential health concern effects were then investigated (Figure 7). The majority of these health effects arose from repeated dose toxicity, mutagenicity, or skin or eye irritant effects (Figure 7A). When the potential health concern polymers were divided into PLCs and non-PLCs, the main observation was that sensitisation effects predominated amongst PLCs (Figure 7B). All other effects were either similar between PLCs and non-PLCs, or predominant amongst the non-PLC polymers. It should be noted that two of these polymers were that reported to show "limited evidence of sensitisation" and another showed a positive *in vitro* but negative *in vivo* genotoxicity test. These polymers may not in fact present a hazard to health, but as the quality of the test data could not be verified, these polymers have been regarded as "potential health concern". For similar reasons, no interpretation of the incidence of specific observed effects was attempted for either group.

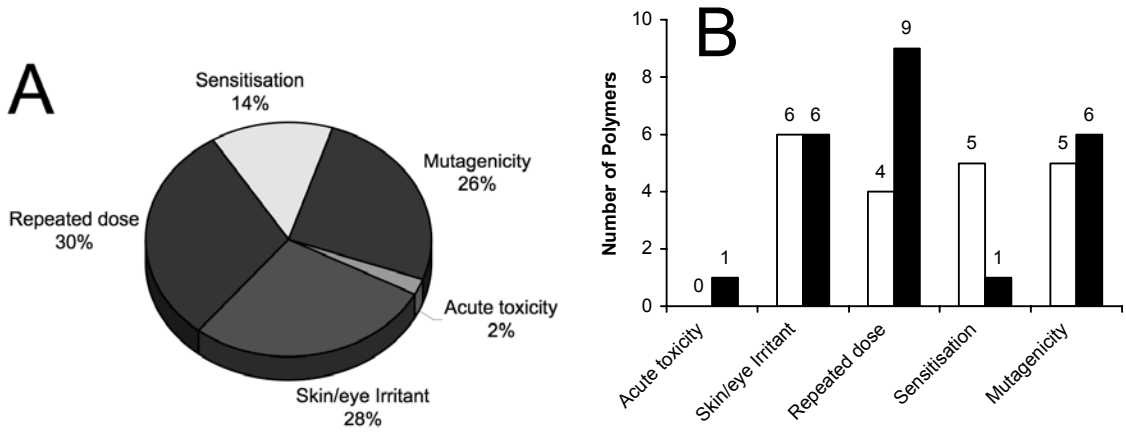


Figure 7.*The potential health concern effects observed in the polymer dataset. (A) The relative incidence of each health effect; (B) health effects observed amongst PLCs (white columns) and non-PLCs (black columns).*

Ecotoxicological data were available for 100 polymers out of 205 (48.8%). The distribution of the maximum ecotoxicological concern rating in the polymer dataset is shown in Figure 8A. Where ecotoxicological data were available, the majority of polymers in the dataset were categorised as low concern for toxicity to Fish, *Daphnia* and/or algae (Figure 8B). Overall, sufficient data were available to carry out some analysis of ecotoxicological parameters. However, this analysis was expected to be somewhat weakened by the scarcity of polymers displaying high ecotoxicological concern (only 6 polymers).

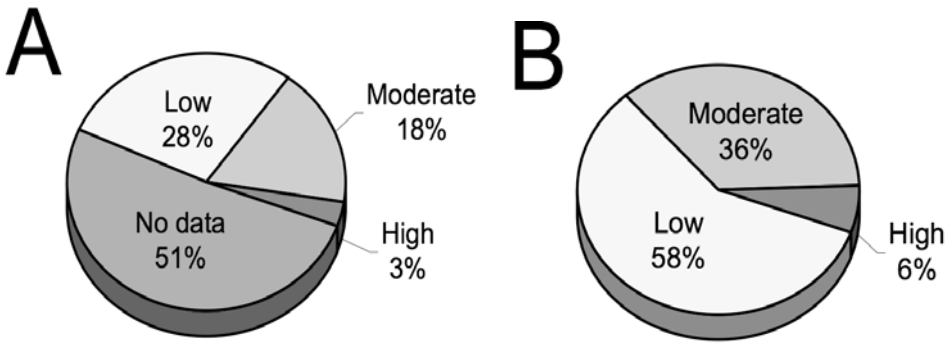


Figure 8. *The polymer dataset by maximum ecotoxicological concern rating. Maximum ecotoxicological concern is shown as (A) a proportion of the total polymer dataset and (B) as a proportion of those polymers which had ecotoxicological data towards any of fish,* Daphnia *or algae.*

The proportions of the entire dataset which exhibit each of the levels of ecotoxicological concern for each species is shown in Figure 9A. The proportion of PLCs and non-PLCs exhibiting each level of ecotoxicological concern for each species examined is shown in figures 9B and 9C, respectively. It is apparent is that fewer findings indicative of ecotoxicological concern were observed amongst the PLCs. The high ecotoxicological concern findings were only observed amongst the non-PLCs, and remarkably more low

concern and fewer moderate concern findings were seen amongst PLCs than amongst the non-PLCs. As it was the largest dataset, the maximal ecotoxicological concern rating out of the three test organisms per polymer (shown in the last column of each panel in Figure 9) was used in many of the following analyses.

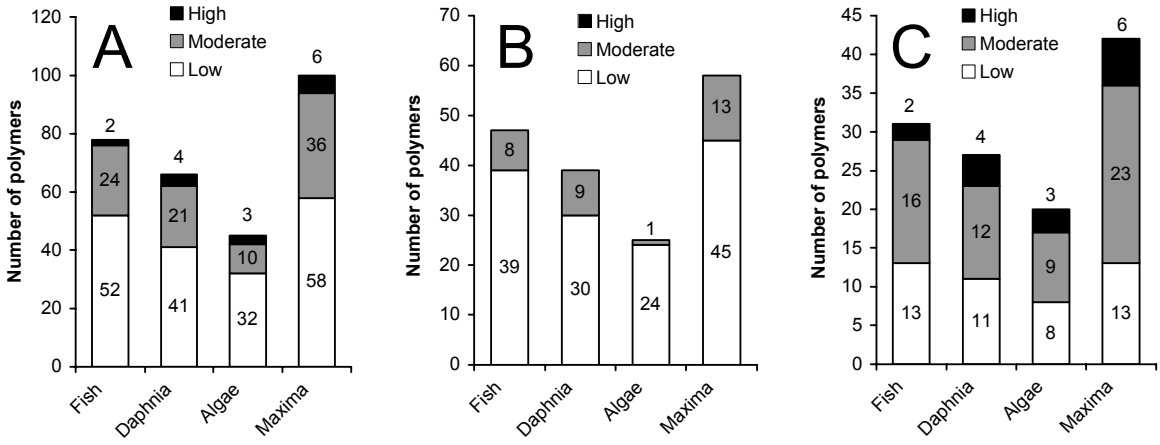


Figure 9. *The number of polymers with each ecotoxicological concern rating for individual lspecies, and the maximum ecotoxicological concern per polymer. (A) All polymers with available ecotoxicological data, (B) PLCs and (C) non-PLCs. The numbers of polymers in each group are indicated within or above column sections.*

Remarks

In general, sufficient data were available to perform a range of analyses on the polymer data gathered. In all cases, some correlation of a polymer's physical or chemical properties with its level of concern to health and/or aquatic environmental toxicity was sought. These analyses are presented below, under headings of each polymer parameter that was investigated.

6.2 Number-average molecular weight (Mn)

Health concern correlation

The most significant and commonly used criterion for establishing a PLC is its Mn range of >1000 Da. This criterion is based on the expectation that smaller molecules will more easily cross biological membranes to cause toxicity. Therefore, as the Mn of a polymer increases, a reduced incidence of potential health concern effects might be expected.

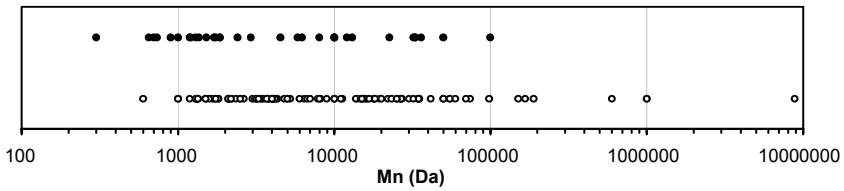


Figure 10. *The distribution of Mn data amongst polymers with low and potential health concern ratings. The low health concern polymer dataset is represented by open circles (○), and the potential health concern dataset by filled circles (●).*

The distributions of Mn values are similar between polymers with low and potential health concern ratings (Figure 10). A lack of very high Mn polymers (>100000 Da) and the presence of several low Mn polymers (<1000 Da) were the only features noted amongst the potential health concern polymers. The overall lack of difference between the groups was also seen in the lack of a statistically significant difference between averages of the two populations ($p > 0.1$). Therefore, a more detailed analysis was required.

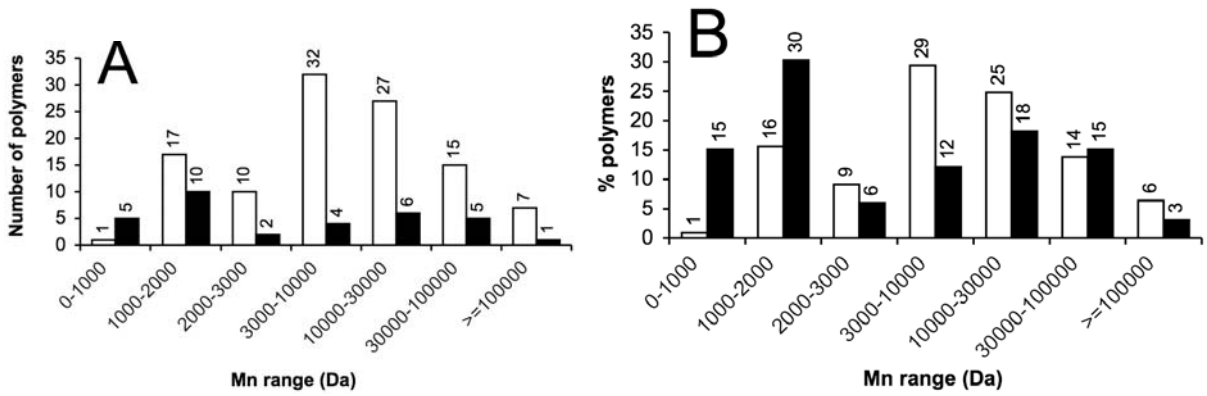


Figure 11. *The proportion of polymers in various Mn ranges, rated as low and potential health concern. (A) The number of polymers in various Mn ranges, and (B) the data of A, normalised as the percentage of the total number of polymers in each health concern rating group. Low and potential health concern are represented by white and black columns, respectively.*

Figure 11 shows an analysis of the number of polymers in various Mn ranges. When the data were analysed by the number of polymers in each health concern group (Figure 11A), correlations of higher toxicity with lower molecular weights were not apparent. The principal observation that was in exception to this is the <1000 Da group, where as expected, a greater number of polymers exhibited potential health concern.

As there were fewer polymers in the potential health concern group than in the low concern group, the number of polymers in each Mn range was normalised to the total number of polymers in each health concern group (Figure 11B). This data treatment revealed a distinct

difference for polymers with Mn <2000 Da, with the potential health concern polymers predominating in incidence. At higher Mn values, the proportions of low and potential health concern polymers in each Mn range were either similar or low health concern-predominant, suggesting that the incidence of polymers with potential health concern may be independent of Mn.

When the specific toxicological effects of polymers rated as potential health concern were compared with their Mn values (Figure 12), no significant differences were found between the means of these different populations ($p > 0.1$). The main observation that can be made is that, as above, the many of these polymers had Mn values <2000 Da (20 of 43 polymers, or 46.5%). This compares with 67 of 205 polymers, or 32.7%, in the wider dataset.

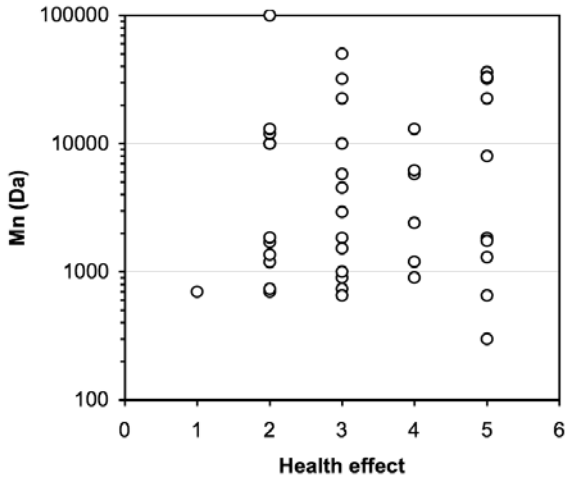


Figure 12. *The Mn distribution of polymers with specific toxicological effects. The health effects were as follows: (1) Acute toxicity, (2) Skin/eye irritation, (3) Repeated dose toxicity, (4) Sensitisation, and (5) Mutagenicity.*

Ecotoxicological concern correlation

To investigate any correlation between Mn and the ecotoxicological concern rating, the data distribution was examined (Figure 13A). Despite the small number of high ecotoxicological concern polymers (only 6 polymers), a trend towards increasing concern at lower Mn was immediately apparent. The average Mn values in each ecotoxicological concern rating, shown in Figure 13B, shows this trend clearly. It can also be seen that most moderate and high ecotoxicological concern polymers have an Mn value of <2000 Da, a value similar to that found for health concern, above.

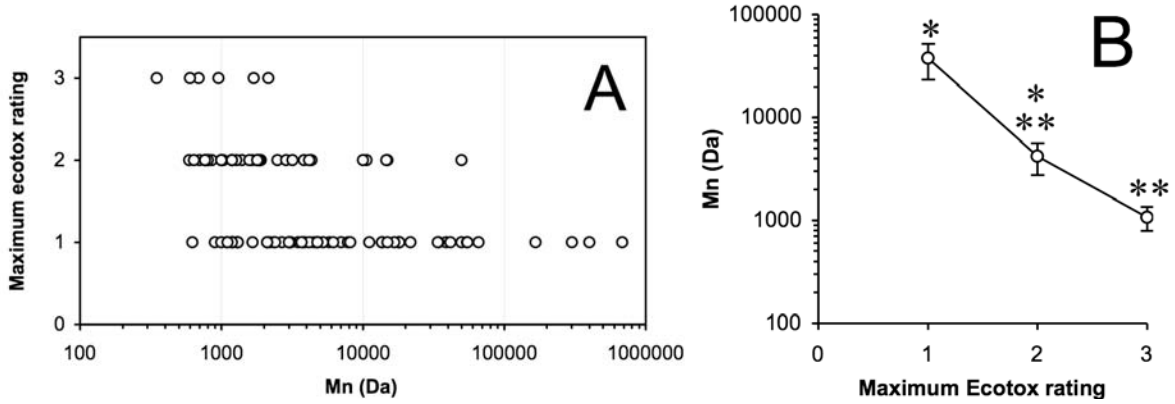


Figure 13. *The influence of Mn on level of ecotoxicological concern. (A) The distribution of Mn data amongst polymers with each maximum ecotoxicological concern rating; (B) the average Mn value for each maximum ecotoxicological concern rating group. Error bars represent the standard error of each group; asterisks indicate statistical significance between data points (* p<0.001; **p <0.05).*

6.3 Oligomer content

Health concern correlation

Another commonly used criterion for establishing a PLC is its oligomer content, and this may be determined for <1000 Da and <500 Da oligomer species. As already described for Mn, this criterion is based on the expectation that smaller molecules will more easily cross biological membranes to cause toxicity. Therefore, it was expected that as the oligomer content increased, a higher incidence of polymers with potential health concern would be observed.

The content of <1000 Da and <500 Da oligomeric species was investigated amongst low and potential health concern polymers (Figure 14). A statistically significant higher mean oligomeric content was found for the polymers with potential for health concern ($p < 0.05$ or < 0.01). However, the low median oligomeric content values show the highly distributed nature of the dataset, and suggest that a small number of polymers with very high oligomeric contents may have influenced the average values.

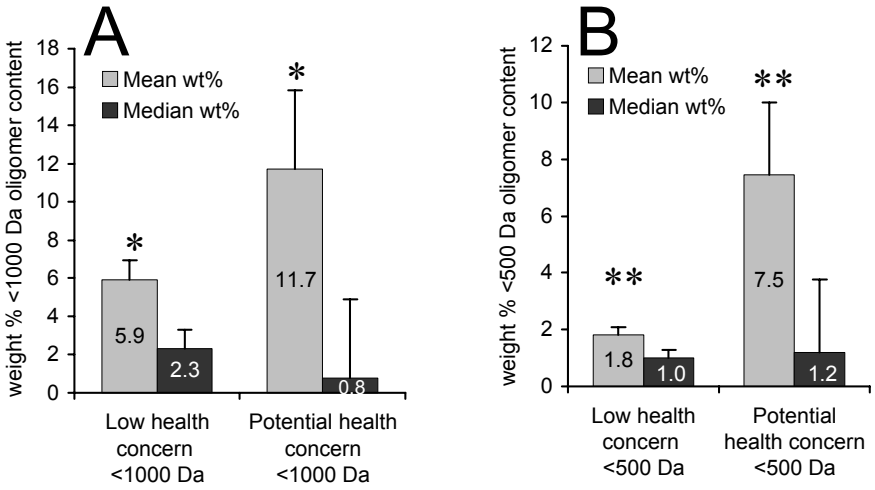
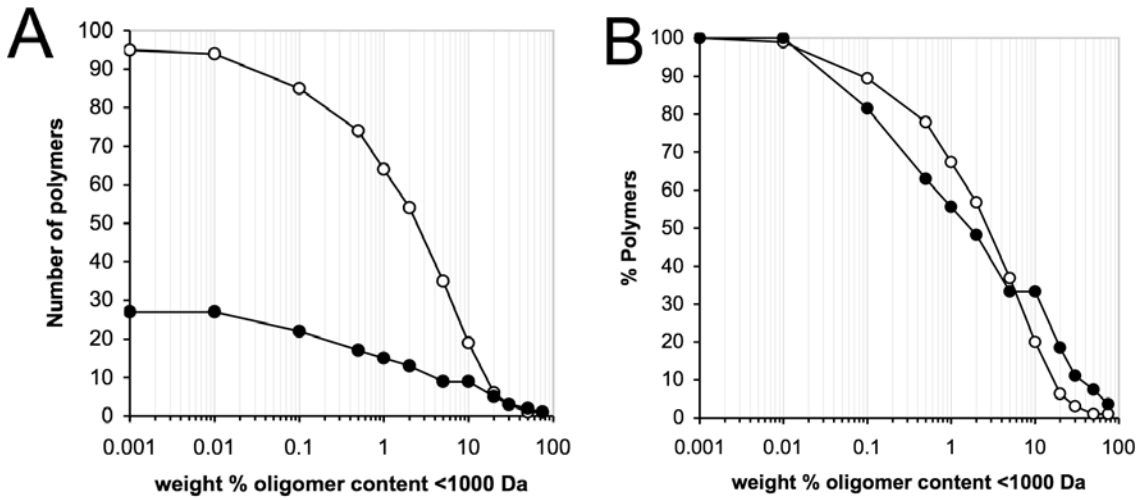


Figure 14. *Analysis of (A) <1000 Da and (B) <500 Da content amongst polymers with low and potential health concern ratings. The error bars represent the standard error of each group. The asterisks indicate statistical significance (* p <0.05; ** p <0.01).*

Further analysis of the dataset was performed using the distribution of non-zero oligomeric content values (to enable the use of a logarithmic scale). Figure 15 shows a representation of the proportions of low and potential health concern polymers with <1000 Da and <500 Da oligomeric content. Low health concern polymers showed an even distribution of oligomer content values. In contrast, the distribution of potential health concern polymers showed an increased incidence of higher oligomer content that began at 5% for <1000 Da and 2% for <500 Da oligomeric content. This observation is enhanced through normalisation of the data, as shown in Figures 15B and 15D.



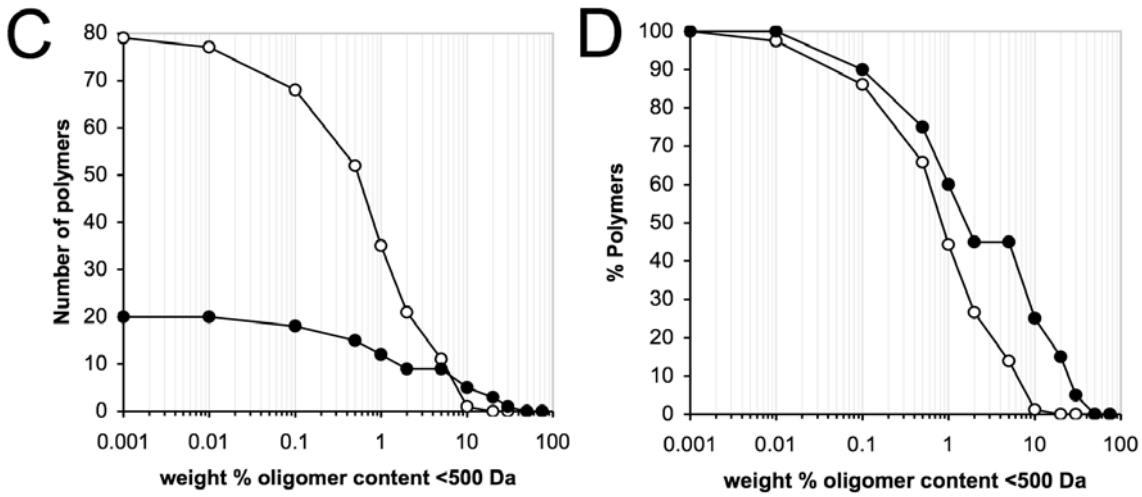


Figure 15. *An analysis of the (non-zero) oligomer content polymers with low and potential health concern ratings. (A) and (B) <1000 Da oligomer content; (C) and (D) <500 Da oligomer content. Panels A and C show the raw data, and B and D show the same data normalised to the total available data within each health concern rating. Low health concern is represented by open circles (○), and potential health concern by filled shapes (●).*

As the oligomer content in many polymers is related to the Mn of the polymer (for example, in polymers with high polydispersity), an analysis of the relationship between Mn, oligomer content and health concern rating was performed (Figure 16). The polymers with potential health concern, as expected, were grouped mainly at combinations of higher oligomer content and lower Mn when compared with the low health concern polymers. Most, but not all, potential health concern polymers had Mn <10000 Da and oligomer content >1%.

Generally, the oligomer content decreased as the Mn increased (Figures 16A and 16B). This was the expected trend, given the distribution of molecular weights present in polymers. However, the nature of the relationship differed between low and potential health concern polymers. Potential health concern polymers showed generally lower Mn values, and so the relationship between Mn and oligomer content was steeper. As a result, there appeared to be mainly low health concern polymers with Mn >10000 Da when <500 Da oligomers were examined. This trend was not as clearly observed using the <1000 Da oligomeric content data.

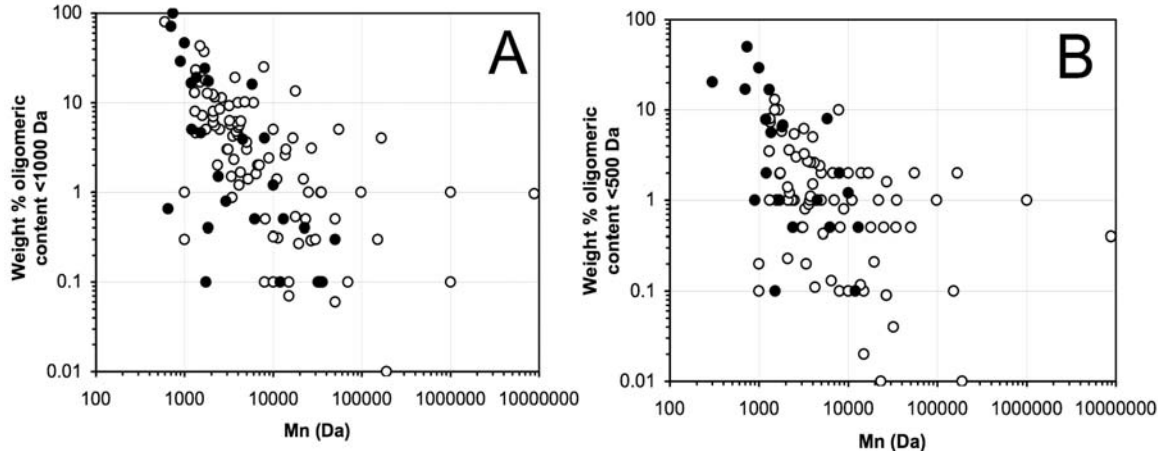
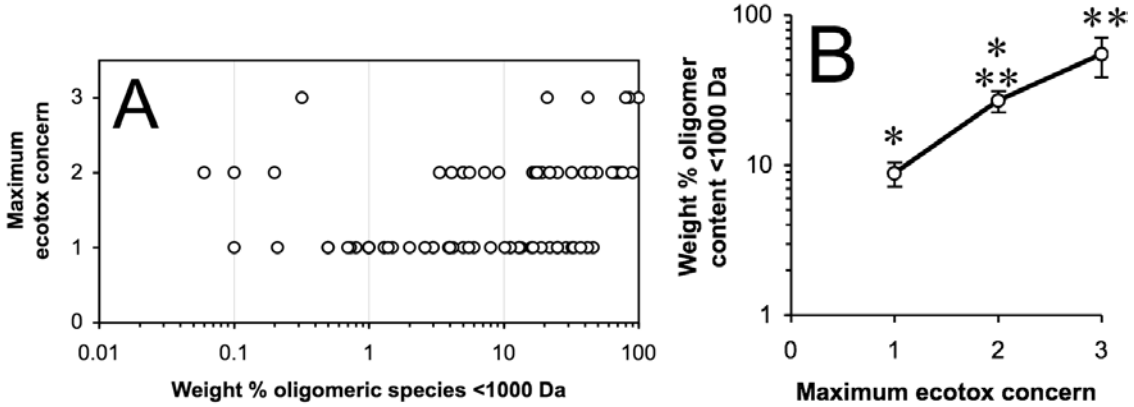


Figure 16. *The relationship between Mn, oligomer content and health concern. (A) <1000 Da and (B) <500 Da oligomer content data. The low health concern polymers are represented by open circles (○), and the potential health concern by filled circles (●).*

Ecotoxicological concern correlation

As with health concern data, the level of ecotoxicological concern would be expected to increase with the content of low molecular weight, oligomeric species. An analysis of the available ecotoxicological concern data in relation to the polymer content of oligomeric species is shown in Figure 17. Despite the few high ecotoxicological concern polymers, the expected trend is observed.

Figure 17A and 17B show clearly that ecotoxicological concern increases progressively for polymers as the content of <1000 Da oligomeric species increases. Figures 17C and 17D show the same trend, but for <500 Da oligomer content. In all cases, the differences between oligomer content for low, moderate and high concern ecotoxicological concern polymers were statistically significant ($p < 0.05$). However, as there were only four high ecotoxicological concern polymers that had available <500 Da oligomer content data, this significance should be interpreted cautiously in the absence of further data.



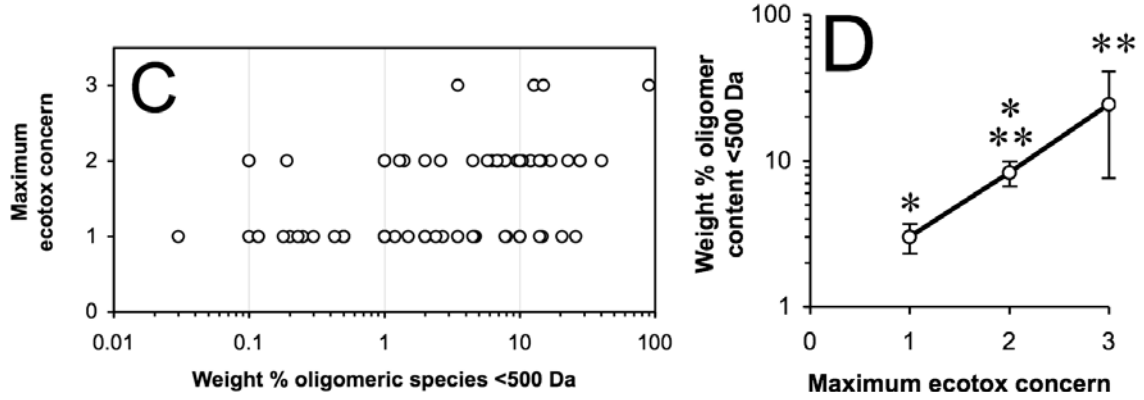


Figure 17. *Comparison of the level of ecotoxicological concern with weight % oligomer content. (A) and (C) show the distributions of <1000 Da or <500 Da data (non-zero values), respectively, for each ecotoxicological concern rating group. (B) and (D) show the average of the available <1000 Da and <500 Da oligomer content data (respectively), for each ecotoxicological concern rating group. The error bars represent the standard error of each group, and asterisks denote a statistically significant difference (* p <0.001; ** p <0.05).*

6.4 Polymer class

Health concern correlation

Separation of the health concern data by polymer class revealed some interesting findings (Figure 18).

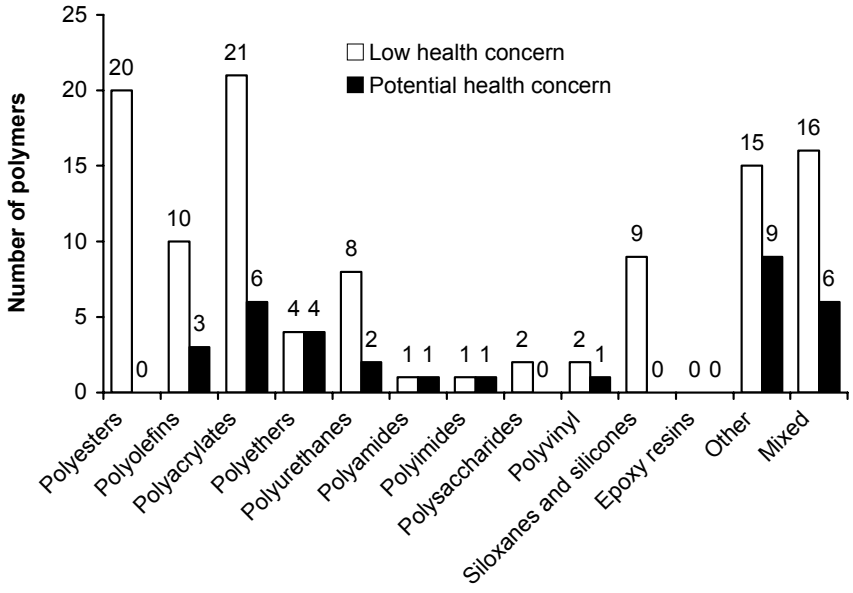


Figure 18. *Polymer class and potential health concern.*

The first of these was that the polyesters, polysaccharides and siloxanes and silicones classes all contained no polymers with potential health concern. With the exception of the polyesters, insufficient polymer data were available to draw any conclusions from this observation.

Several classes showed a number of potential health concern polymers, but the significance of this is unknown given the small number of polymers. Some classes (e.g. polyacrylates) may have higher toxicity due to their propensity to contain hazardous residual monomers. The high incidence of potential health concern in the "mixed" and "other" groups is also of unknown significance, given their uncertain chemistries.

The Mn and oligomer content of each polymer class, in combination with or apart from their chemistry, was then analysed to investigate the incidence of potential health concern polymers in specific polymer classes (Figure 19).

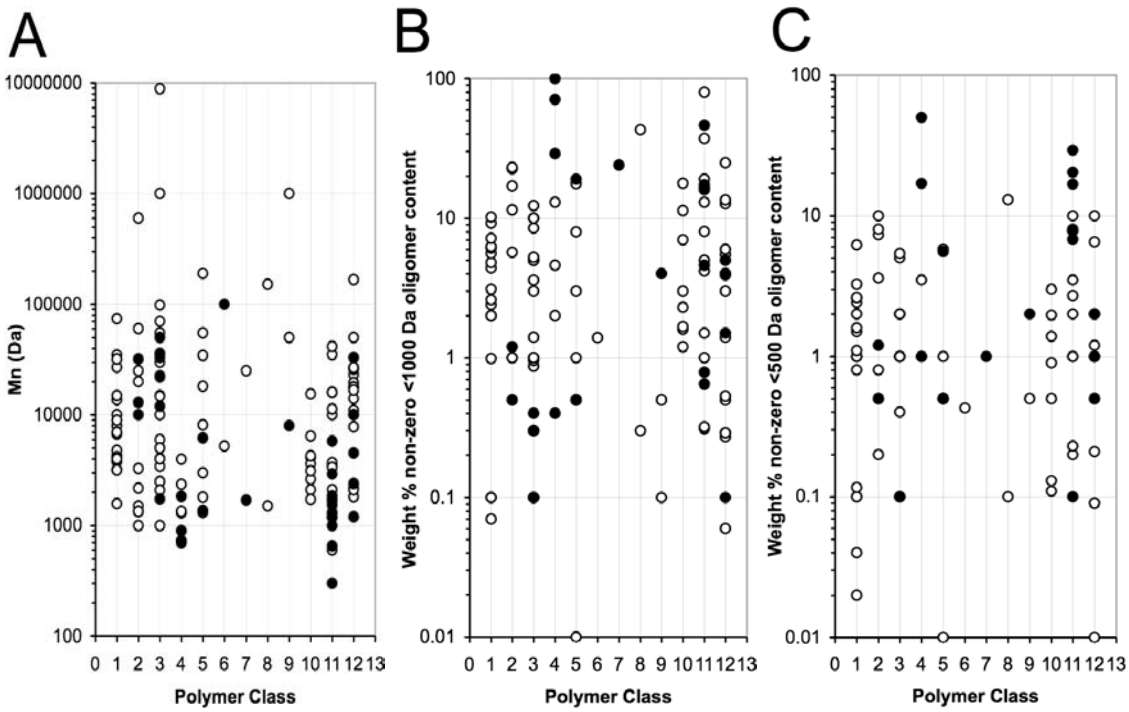


Figure 19.*The distributions of Mn and oligomer content data in various polymer classes, for low and potential health concern polymers (represented by open (○) and filled circles (●), respectively). (A) Mn data; (B) <1000 Da and (C) <500 Da oligomer content. Only non-zero oligomer content data is represented.*

Key to polymer classes: *1: Polyesters, 2: Polyolefins, 3: Polyacrylates, 4: Polyethers, 5: Polyurethanes, 6: Polyamides, 7: Polyimides, 8: Polysaccharides, 9: Polyvinyl, 10: Siloxanes and silicones, 11: Other, 12: Mixed, 13: Epoxy resins.*

Figure 19A shows that when low and potential health concern polymers were analysed by both polymer class and Mn, some polymer classes contained predominantly lower molecular weight polymers (e.g. polyethers). Also, it is interesting to note that the lower Mn polymers in some polymer classes appeared more likely to be of potential health concern (e.g. polyethers, polyurethanes), while in others potential health concern did not appear to be related to Mn (e.g. polyolefins, polyacrylates).

Figures 19B and 19C show the low and potential health concern polymers of each polymer class analysed by <1000 Da and <500 Da oligomer content (respectively), and it can be seen that the data seems to show similar features to the analysis above for Mn. The expected trend of higher oligomeric content predisposing a polymer to potential health concern only appeared to apply in specific polymer classes. Some (notably polyacrylates and polyolefins) appeared to display higher potential health concern where the oligomer content was minimal. The cause(s) of these phenomena have not been investigated further, as they may be artefacts of the limited datasets for each polymer class. Nonetheless, it is interesting to speculate that low molecular weight species with particular chemistries might be more likely to result in health concern than others. It is also possible that some polymer classes, while polymerising to high degrees, may contain a high content of toxic residual monomer species that could account for their potential health concern.

Polymers of particular polymer classes may potentially produce particular health effects, but the analysis performed to investigate this gave no meaningful results (data not shown). This failure was attributed to the small numbers of polymers available with health effects, and to the large proportion of “mixed” and “other” classes among these.

Ecotoxicological concern correlation

An analysis of the ecotoxicological concern data by polymer class is shown in Figure 20. Ecotoxicological concern does not appear to follow a similar trend by polymer class as that observed for health concern (Figure 18). In particular, polyesters, polyacrylates and polyethers showed significant numbers of polymers displaying moderate or high ecotoxicological concern. Ecotoxicological data was scarce in several polymer classes.

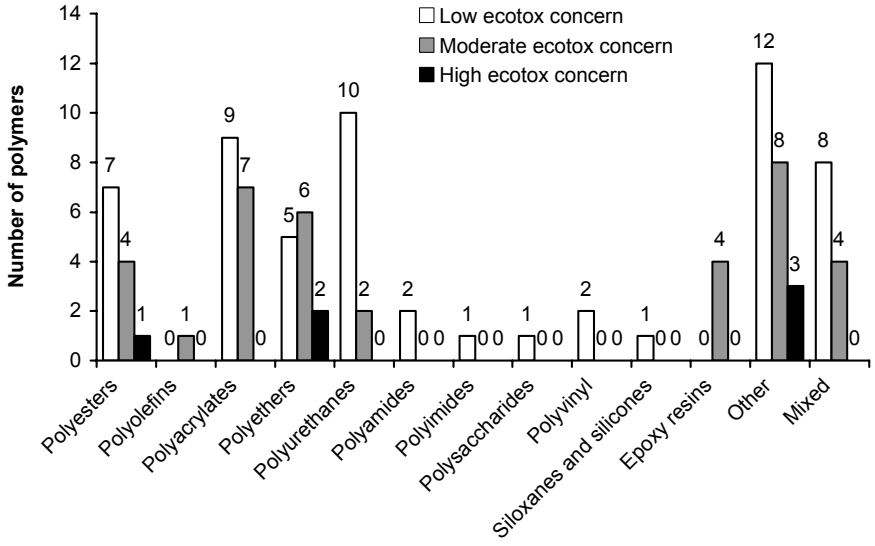


Figure 20.*The available ecotoxicological concern data, presented by polymer class.*

Some relationship between Mn and the level of ecotoxicological concern is suggested within each polymer class (Figure 21). This trend is similar to that observed above for health concern data (Figure 19), and as seen in the analysis of ecotoxicological concern by Mn alone (Figure 14). In general, the highest ecotoxicological concern polymers within each polymer class presented at the lower end of the Mn range each class of polymer. Most of the polymers with moderate and high ecotoxicological concern had Mn values of <2000 Da, and <1000 Da oligomer contents of >5%.

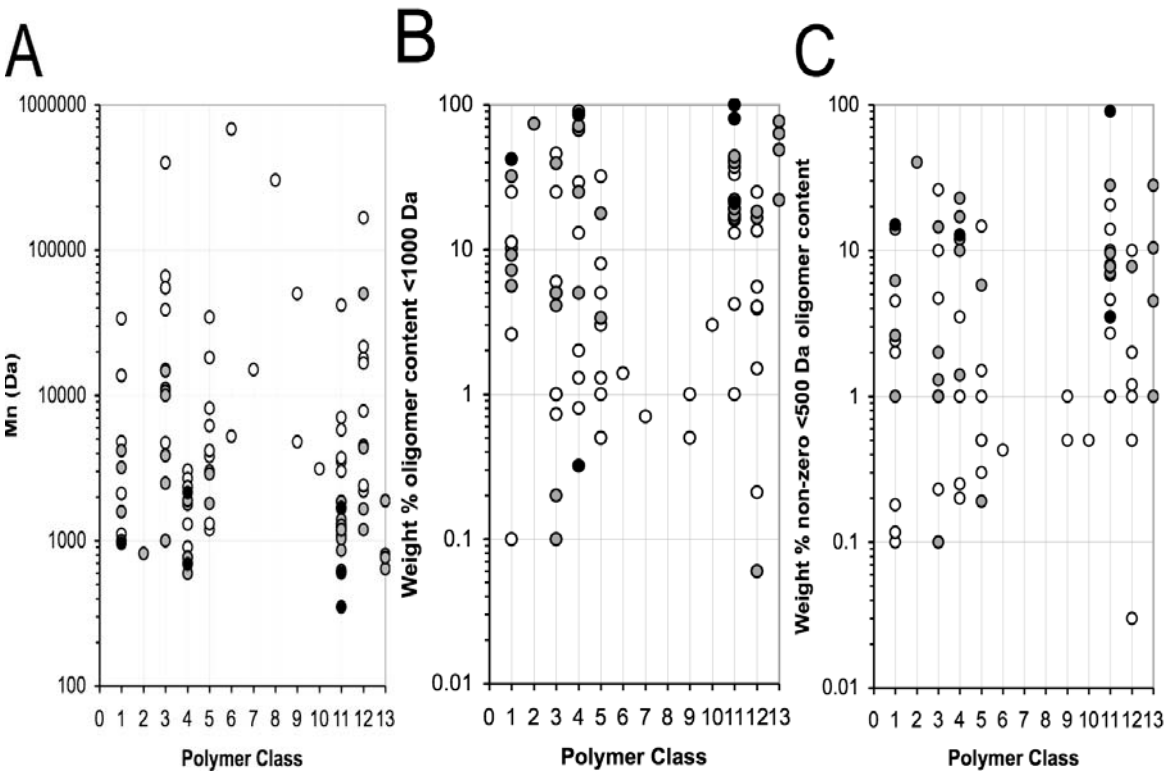


Figure 21. *The relationship of Mn, oligomer content and polymer class on ecotoxicological concern. (A) Mn, (B) <1000 Da oligomer content and (C) <500 Da oligomer content. The low ecotoxicological concern polymer dataset is represented by open circles (○), moderate concern by grey-filled circles (●) and high concern by black-filled circles (●).*

Key to polymer classes; *1: Polyesters, 2: Polyolefins, 3: Polyacrylates, 4: Polyethers, 5: Polyurethanes, 6: Polyamides, 7: Polyimides, 8: Polysaccharides, 9: Polyvinyl, 10: Siloxanes and silicones, 11: Other, 12: Mixed, 13: Epoxy resins.*

6.5 Reactive functional groups (RFGs)

Health concern correlation

A reasonable hypothesis when investigating RFGs would be that a group of polymers containing RFGs might be more likely to display potential health concern than would a group of polymers that did not contain RFGs.

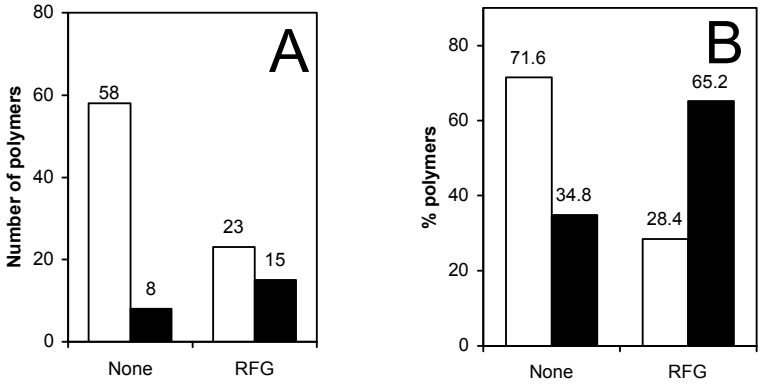


Figure 22.*The presence of RFG-containing polymers in the low and potential health concern datasets. (A) The total number of polymers, and (B) normalised as the percentage of the total number of polymers with each health concern rating group.*

A greater proportion of the polymers in the potential health concern dataset were found to contain RFGs than were present in the low health concern dataset (Figure 22). However, when the two health concern datasets were compared, the average RFG rating in each was not found to be significantly different ($p > 0.1$).

Due to the limited RFG data in the polymer dataset, a detailed analysis of individual RFGs was not expected to be possible. An attempt was made to represent the different RFGs in regards to potential health concern (Figure 23). The majority of RFGs that are described in the PLC criteria as "high concern" were poorly represented. Notable exceptions to this were amino and epoxide groups, and unsubstituted positions *ortho*- to a phenolic hydroxyl; these RFGs were found in a number of polymers with potential health concern.

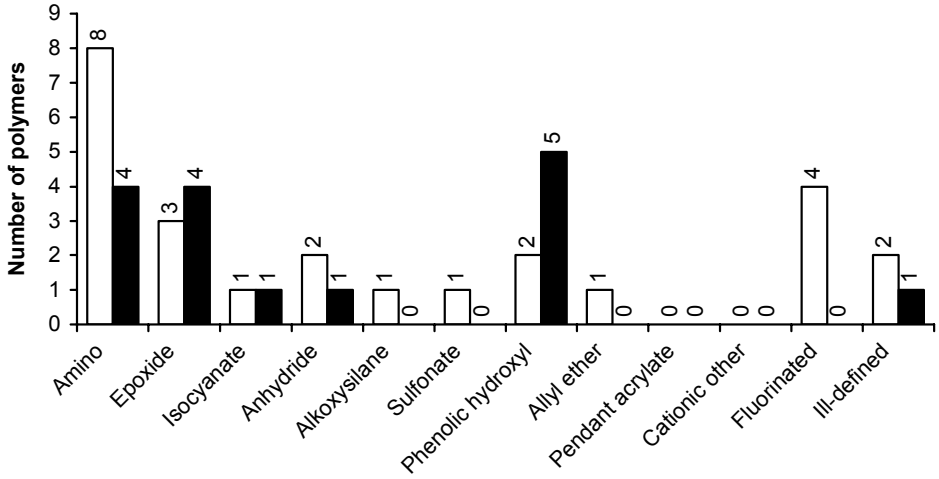


Figure 23. *The occurrence of specific RFGs within the low and potential health concern datasets (white and black-filled columns, respectively).*

As the FGEW of a polymer is descriptive of its content of RFGs, some attempt was made to analyse this data (Figure 24). It might have been expected that as the health concern rating of the polymers increased, the FGEW would decrease. However, insufficient FGEW values were available to make any conclusions, and no trend was apparent. No statistically significant difference was found between the average FGEWs of the two health concern groups ($p > 0.1$).

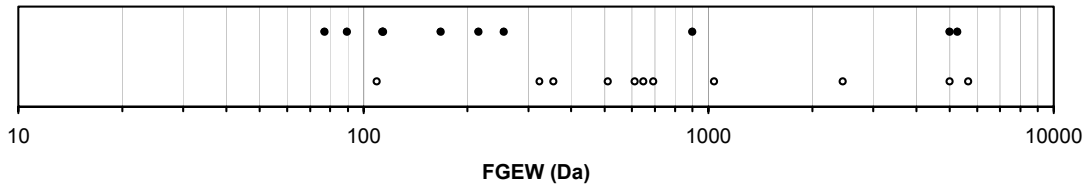


Figure 24. *The FGEW distributions amongst polymers with health concern data. The low health concern polymer dataset is represented as open circles (○), and potential health concern polymers as filled circles (●).*

Ecotoxicological concern correlation

The expected trend, that more moderate and high ecotoxicological concern polymers would contain RFGs than would low concern polymers, is shown in Figure 25. More polymers in the moderate and high concern datasets contained RFGs than did polymers that contained no RFGs (Figure 25A). As the level of ecotoxicological concern increased, the proportion of the ecotoxicological concern dataset that contained RFGs also increased (Figure 25B). This trend was not considered to be strong overall, because of the small numbers of RFG-bearing polymers with high ecotoxicological concern data.

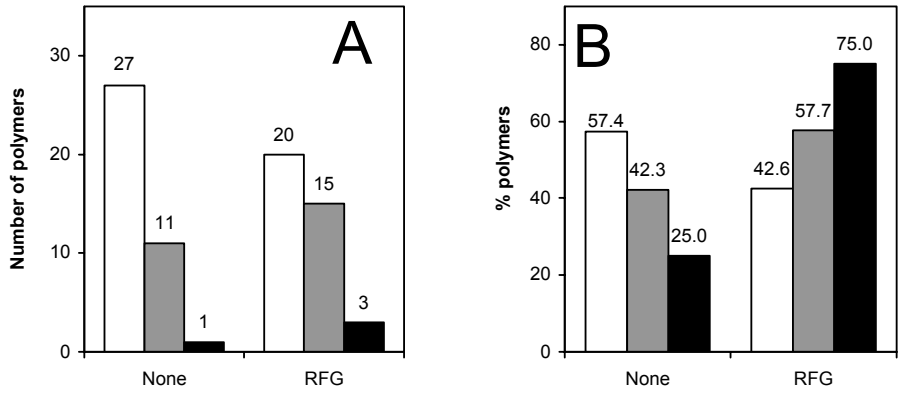


Figure 25. *RFG-containing polymers in the low, moderate and high ecotoxicological concern datasets (shown as white, grey and black-filled columns, respectively). (A) The total number of polymers containing no RFGs ("None") or RFGs, and (B) the data in A, normalised as the percentage of the total number of polymers.*

A similar general lack of representation of any specific RFG, as seen for potential health effects, can be observed for ecotoxicological concern in Figure 26. The main exception to this was in the data for containing amino group-bearing polymers, where a large number of

moderate and high ecotoxicological concern polymers were found. Three of the six high ecotoxicological concern polymers had amine groups, two had "not determined" RFGs and one was claimed to have no RFGs.

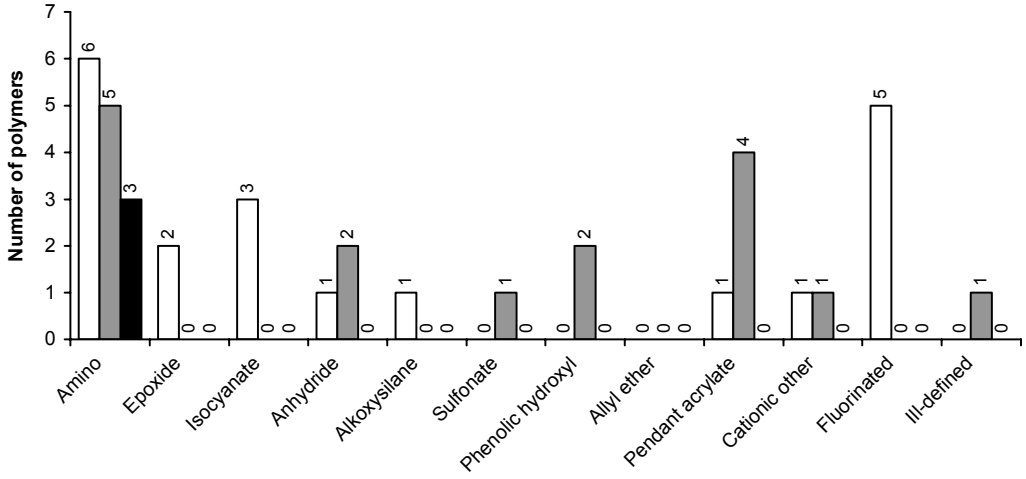


Figure 26. *The occurrence of specific RFGs within the low, moderate and high potential ecotoxicological concern datasets (shown as white, grey and black-filled columns, respectively).*

An attempt was made to analyse the FGEW data within the ecotoxicological concern dataset (Figure 27). It might have been expected that as the ecotoxicological concern of the polymers increased, the FGEW would decrease. Figure 27B shows that the average FGEW of moderate and high ecotoxicological concern polymers was generally lower than that of low concern polymers, but this was not found to be statistically significant ($p > 0.1$). Overall, insufficient FGEW values were available to make any conclusions.

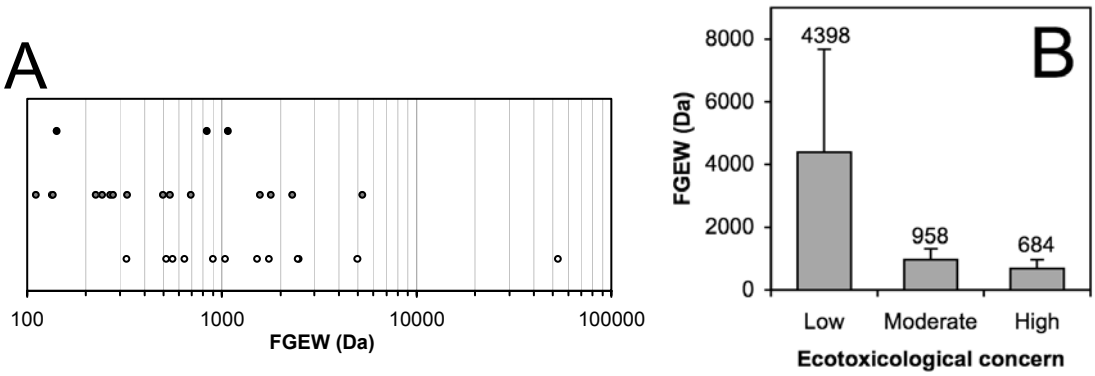


Figure 27. *The relationship of FGEW and ecotoxicological concern. (A) The distribution of FGEW values in the ecotoxicological concern dataset, and (B) the average FGEW values within each level of ecotoxicological concern. The low ecotoxicological concern polymer dataset is represented by open circles (○), the moderate by grey-filled circles (●) and the high by black-filled circles (●). The error bars denote the standard error of each group.*

6.6 Water solubility/extractability

Health concern correlation

A hypothesis of the contribution of water solubility towards potential health concern would be that some water solubility is required for a polymer to exhibit toxicity. However, polymers that are very water-soluble might not be expected to be able to cross biological membranes.

The distribution of water solubility data for low and potential health concern polymers is represented in Figure 28. The average water solubilities in these groups were not found to be significantly different (p >0.5).

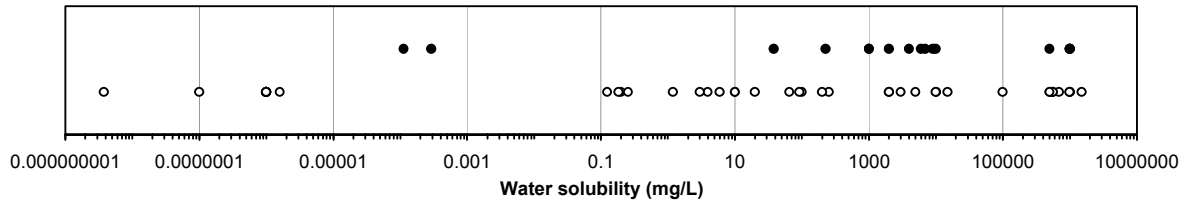


Figure 28.*The distribution of water solubility data amongst polymers with low and potential health concern ratings (represented as open circles (○), and filled circles (●), respectively).*

In Figure 28, it was noted that most of the polymers with potential health concern displayed water solubility of >10 mg/L but <100000 mg/L. Therefore, the water solubility data were then further analysed, to see if any water solubility ranges would exhibit lower or higher potential for health concern (Figure 29).

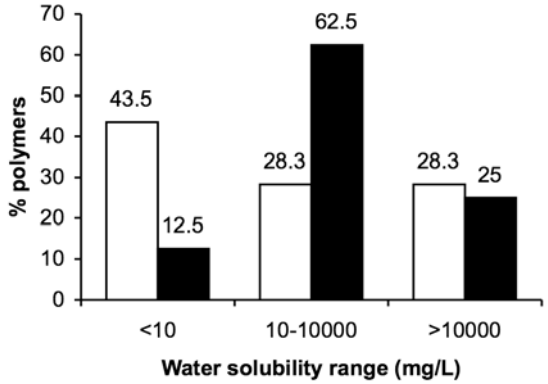


Figure 29.*Water solubility data for polymers with low and potential health concern ratings (represented by white and black columns, respectively). The numbers of polymers in the indicated water solubility ranges were normalised as the percentage of the total number of polymers in each health concern group.*

Several observations were made. Firstly, a greater proportion of low concern polymers showed very low water solubilities (<10 mg/L). Secondly, the proportions of polymers of low and potential health concern were similar at higher water solubilities (>10000 mg/L)

suggesting that these polymers are no more or less likely to display health concern. Thirdly, and perhaps most significantly, a greater proportion of potential health concern polymers were found at intermediate water solubilities (10-10000 mg/L). This may indicate that the intermediate water solubilities of these polymers may contribute in some way to their ability to cause toxicity.

Ecotoxicological concern correlation

Higher water solubility was generally observed for polymers with moderate and high ecotoxicological concern (Figure 30). However, no statistically significant difference was observed between the average water solubilities of low, moderate and high ecotoxicological concern polymers ($p > 0.1$). The wide distribution within the data and the limited high concern ecotoxicological data prevented any further analysis.

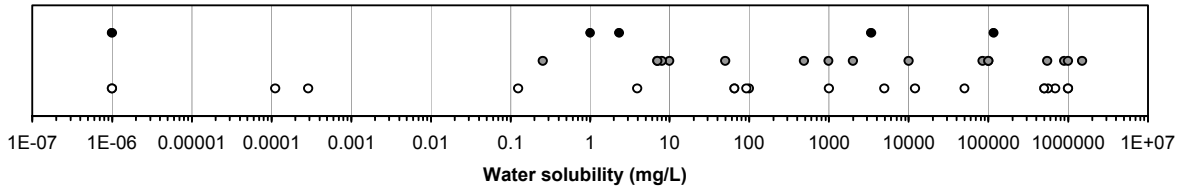


Figure 30. *The distribution of water solubility data by ecotoxicological concern rating. The low ecotoxicological concern polymer dataset is represented by open circles (○, lower), moderate by grey-filled circles (●, middle) and high by black-filled circles (●, upper).*

7 Conclusions

7.1 Observations in the context of the PLC criteria

Overall, this initial analysis provided scientific evidence that builds confidence in the PLC criteria (where sufficient data were available). The contention that polymers meeting the criteria have insignificant human health or environmental impact was supported, which in turn supports reduced regulatory requirements for these polymers.

Low health concern was observed for 87.8% of PLCs, despite the conservative approaches used for classifying the level of health concern. This value represents the outcome of this initial analysis, given the level of confidence in the available data. Should the quality of the data and analytical techniques be further refined, this value is expected to increase.

A minority of polymers that met the PLC criteria exhibited some potential for health concern (17 of 139 polymers, or 12.2%), although this may not be a reflection of the hazard of these polymers. No explanation for these effects was apparent from the data available. Some explanations might include:

1. The observed health effects were caused by a mechanism not effectively covered by the data collected (e.g. hazardous residual monomers);

2. The effects were caused by a mechanism that is not addressed by the PLC criteria; or

3. The potential health concern assigned to these polymers was an analytical artefact, resulting either from the brief nature of the data available, or from the assumptions and methods of analysis used.

Both ecotoxicological and health concerns appeared to inversely correlate with **number-average molecular weight** – the higher the Mn, the lower the concern. From the available health concern data, it appears that polymers with a Mn <2000 Da have a higher incidence of potential health concern. Similarly, a direct relationship between decreasing Mn and increasing severity of ecotoxicological concern was observed. It should be noted that several polymers with higher molecular weights (Mn >1000 Da) exhibited potential health and ecotoxicological concern. It is presumed that these polymers caused their toxicity through mechanisms that did not require the polymer to cross biological membranes. This correlates to some extent with the PLC criterion of Mn >1000 Da; however, the analysis herein would suggest that the existing criterion, in isolation, might not capture all polymers that display high concern effects.

From the analysis presented herein, some levels of **oligomer content** were suggested as being associated with potential health concern. Potential health concern polymers were seen with greater incidence at >5% of <1000 Da oligomeric species and at >2% of <500 Da oligomeric species. When oligomer content and Mn were concurrently analysed, it was found that while most potential health concern polymers had Mn <10000 Da and oligomer content values of >1%, some had values outside these ranges. For ecotoxicological concern, a clear trend to

increasing concern with increasing oligomer content was observed. These analyses agree to some extent with the PLC criterion for polymers with Mn >10000 Da, but do not support the allowable oligomer content in polymers with Mn of 1000-10000 Da (<25% for <1000 Da species and <10% for <500 Da species).

Overall, insufficient data were available to find any correlations between **polymer class** and increased health or ecotoxicological concern. Of note was the absence of potential health concern polymers amongst polyesters, suggesting that these polymers may be of inherently lower toxicity. Some higher incidences of potential health concern appeared in some polymer classes, but in only some classes was the influence of low molecular weight species suggested. The influence of low molecular weight species was suggested more strongly in the polymer classes that contained polymers with ecotoxicological concern. Other than polyesters made from specified reactants, polymer class is not a criterion used for determining a PLC.

The presence of **reactive functional groups** was more common amongst polymers that displayed potential health or ecotoxicological concern. Three RFGs were present in a number of potential health concern polymers: amino and epoxide groups, and unsubstituted positions *ortho*- to a phenolic hydroxyl. Amongst the small number of polymers with ecotoxicological concern, half contained amino groups. Due to the lack of correlation between FGEW in an initial analysis, no attempt was made to further correlate FGEW with health or ecotoxicological concern. Overall, there was insufficient data available to validate the level of concern for any RFG in the PLC criteria.

Analysis of the **water solubility** data for the polymers with either health or ecotoxicological concern suggested some influence of water solubility on the level of concern they presented. For health concern, polymers with very high or very low water solubility appeared to not display potential health concern. Intermediate water solubilities (10-10000 mg/L) were found to contain the majority of potential health concern polymers in the dataset. In contrast, ecotoxicological concern polymers tended to have water solubilities of >10 mg/L. Water solubility is not a widely accepted criterion for defining a PLC.

Overall, each of the polymer parameters analysed supported the applicability of the PLC criteria (where sufficient data were available). Given that the PLC criteria are not applied in isolation, it was striking that many of the criteria covered the point at which greater health and/or ecotoxicological concern was observed in this initial analysis.

7.2 Data and analytical weaknesses

Several weaknesses or inadequacies were noted in the data and methodology of this initial analysis. The most significant of these resulted from a lack of data in some critical areas. For example, data on a broad range of health endpoints were not available for most polymers.

Firstly, **no analysis of specific toxicological effects could be meaningfully conducted**. Insufficient data were available; there were only 33 potential health concern polymers and 6 high ecotoxicological concern polymers in the dataset. The analyses were consequently hampered, and many of the trends should only be interpreted cautiously. Further data will be required to carry out analyses of specific health or ecotoxicological effects. Future analyses,

where a greater depth of toxicological information might be available, should be conducted in such a way that toxicological end-points are considered both individually and in a grouped fashion (e.g. for a specific mechanism of action).

- The system used in this analysis to assign polymers on the basis of limited toxicological data into concern ratings may be overly simplistic. In this way, a polymer may not be a hazard to human health but may still have been included in the analysis as being of potential health concern (e.g. a positive *in vitro* mammalian chromosomal aberration study result may not be relevant in the context of other negative genotoxicity testing).

- The available data did not include a comprehensive suite of toxicological or ecotoxicological studies for each polymer. Therefore, a polymer may have a health or ecotoxicological concern that may not have been identified during this analysis.

- In all cases, it was unknown if the collected polymer parameters were those for the actual polymers that were used to conduct the health and ecotoxicological toxicity testing. Batch-to-batch variability or different industrial requirements may have meant that testing was carried on a different species than was used to generate the other parameters used for the analysis presented here. Given the sources of the data, this weakness in the data will be difficult to overcome.

Secondly, **the collected data could not describe all of the PLC criteria**. In particular, deficiencies were noted in the information for reactive functional groups, polymer class and residual monomers, and in the classification of health effects and PLC/non-PLC status.

- There were insufficient data available on reactive functional groups to carry out detailed analyses. In addition, the FGEW data provided was too incomplete to be useful (in several instances, "<5000" or "0" values were provided for polymers with RFGs). Additional data will be required for any more detailed analysis of polymer RFGs.

- The available data does not adequately report the health or ecotoxicological concern that might be presented by residual monomer species in the polymers. The majority of the examined polymers were reported to contain some of these species, yet the contribution of these to the polymer's level of concern was unknown. Future analyses should collect data on these species for each polymer, including their concentration and known hazard(s).

Thirdly, **the necessity for conservative assumptions may have influenced the analyses.** These assumptions were needed because of the inconsistent approach to data collection. Much interpretation was required to refine the data into a useful form for analysis.

- The classification of each polymer as a PLC or non-PLC was not required at the data collection stage, and this required the classification of polymers based on insufficient data. The PLC status of 14 polymers had not been confirmed at the time of writing. Note that only two of the potential health concern PLCs were amongst these polymers.

- Similarly, there was no consistent approach to the interpretation of original data, including for the classification of the polymers as PLCs or non-PLCs. It is not known how much subjective interpretation was used by each jurisdiction when providing experimental data, and the data could only be used as it was provided. Subsequent re-interpretation and refinement of the data during the analyses may have compounded errors.

Last, **most of the analyses did not consider the interaction of multiple polymer parameters to the level of concern**. If sufficient data were available, future analyses might attempt to correlate multiple parameters for each polymer to determine if synergism might contribute to the level of concern for toxicological or ecotoxicological effects.

7.3 Future directions

This initial analysis concludes the first stage of the polymer work agreed at the Tokyo Expert Group Meeting (March 2007), meeting the objectives of providing a correlation that PLCs generally have insignificant human health or environmental impacts. It builds confidence in the concept that PLCs should have reduced regulatory requirements.

However, there is much that could be achieved in further work on polymers aimed at refining and widening the scope of the PLC criteria. In particular, further analyses that focus on each of the PLC criteria will strengthen the initial analysis in this report.

Specific aims for future work might include:

1) To refine and strengthen the analyses conducted thus far, especially in regards to the interpretation of original data (removing the need for conservative assumptions), addressing insufficiencies in the dataset, and improving any other weaknesses in the initial analysis;

2) To analyse data on specific health and environmental effects of polymers, to better understand their mechanisms of toxicity; and/or

3) To refine or broaden the PLC criteria, improving their ability to discriminate between polymers that might, or might not, exhibit toxic effects. Such work would require at least the above aim (1) to be fulfilled, so that any changes to PLC criteria are made on the basis of the best possible information.

Based on the experiences from this initial analysis, considerable work will be required to collate and carry out further analyses. However, by applying the knowledge gained from this analysis, improved methods of data collection, interpretation and analysis may be achieved.

8 List of Contributors

OECD Secretariat, New Chemicals Taskforce, Work Item B group

Nathalie Delrue, Richard Sigman

Australia

Adam Brymora (Primary Author)
Bob Graf
Hana Hamdan
Jennifer Turner
Louise Stedman

Canada

Andy Atkinson
Annabel Pigeon
Chris Whynot
Jonathan Tigner
Karen Mailhiot
Myriam Hill
Tim Singer

Japan

Chie Fujita
Fumiaki Shono
Hideaki Tanaka
Yumiko Hata

United States of America

Anna Coutlakis
Paul Bickart

Business and Industry Advisory Committee (BIAC)

Craig Barker
Jack Soule
Marianne U. Heinrich
Mike Irwin