Examination of the term ‘Sensitizing’ in the context of the methodology for determining hazardous waste and chemicals classification procedures under the new EU Waste Framework Directive

Briefing Note of JULIAN ISKEN’S MSc THESIS

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Objectives:
Four main objectives were identified:

1. to determine why the criterion ‘Sensitizing’ has been introduced in the Waste Framework Directive
2. what methodology is used to determine hazardous waste properties
3. which assays are available to test substances and mixtures on their sensitization potential
4. which impacts will the changes have on industry

Introduction
The Waste Framework Directive (WFD) [2008/98/EC] lays out the basic principles of waste management within the European Union. In 2008 the WFD has been revised. Apart from other changes, the new WFD includes now a longer list of properties of waste that render waste hazardous. One of the newly introduced properties is: H13 ‘Sensitizing’. The WFD describes ‘Sensitizing’ as ‘substances and preparations which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitization such that on further exposure to the substance or preparation, characteristic adverse effects are produced.’

At first glance similar definitions can be found for other categories and the directive also provides a restriction to the category H13 that this category is only applicable ‘As far as testing methods are available’.

It is very likely that the newly introduced category H13, and some modifications in the already existing H-categories, will have an impact, for example they will probably increase the total amount of wastes which are considered as hazardous. If this happens, national and local waste management authorities need to prepare themselves for larger amounts of hazardous wastes and they need to be able to identify and distinguish between the categories in the WFD. Producers might want to prevent their products from being considered as hazardous wastes and therefore need to know exactly which substances and preparations fall under the hazardous waste categories. Additionally, some preparations and substances might need to be re-classified under the new Directive.

This thesis discusses the question why the category has been introduced and what differences it will make for waste holders and industry; it determines why the new criterion has been introduced, which methodology is currently in use to determine the properties in the WFD and which testing methods are available.
Methodology
The methodology is mainly based on a literature review. Legislative documents, meeting papers, articles from medical, chemical and toxicological journals and books have been the primary sources. Furthermore an Impact Assessment has been employed to predict the effects of the WFD on regulators and waste holders. The Impact Assessment was performed using the official guidance of the EU as far as sensible. Because there was insufficient data to calculate many of the results, most of them were based on reasoned assumptions.

Results
The examination of the term ‘Sensitizing’ has led to the conclusion that sensitizing as a chemical hazard property is nothing completely new or unknown. Until recently, the technical difficulties to test chemical compounds and in particular waste on its sensitizing capabilities deterred the legislator from including it in the hazardous waste properties list. The improved test methods and the political will to harmonize waste and CLP regulations have led to a change of mind. Due to the better and also more ethical new assays, testing can be performed cheaper and with increasing reliability. The limitation in the legislation that sensitizing as a criterion only applies as far as testing methods are available is a reasonable concession to industry and waste holders, because test methods have still not reached a sufficient degree of reliability and for some types of sensitization there are no tests at all.
The amount of hazardous waste will increase.

Discussion, Conclusions and Policy Implications
Sensitizing has been introduced in the WFD because of recent improvements in testing methods, which make testing for sensitizers more reliable and cheaper. Another reason was the aim of the EU to harmonise several legislations and have similar property lists in those acts.

Predicting the exact costs for waste holders and authorities is impossible as long as precise data of the amount of the newly as hazardous waste classified wastes are missing. But it can be expected that an increase in hazardous waste will always lead to increasing costs.
In general it might be useful to collect data on how much hazardous waste is disposed of for each hazardous property criterion. This would help to find out how important the different criteria are in reality, how much money each category costs and how much waste of each type waste managers need to deal with. This could also be used as a basis for a cost benefit analysis.

In terms of the testing methods it is obvious that the currently available testing methods are not sufficient and that further research is needed. But there have been considerable improvements in the test assays in the last decade.
The most important question in terms of the WFD is if the test methods are applicable to hazardous waste. The currently available testing methods were all developed for chemicals and not for the testing of mixtures or preparations. Only in a few cases will waste consist of single, isolated chemicals that can be tested. Most of the waste will probably consist of old products, packaging or a mixture of both. So currently there are no tests available that are designed to test hazardous waste and there is no assay for substances or preparations for respiratory sensitizing.

Furthermore, different scholars agree that it would be beneficial if there were a reference list of chemicals which were already known as strong skin sensitizers. Every testing method could be applied to this list to see if it delivers an acceptable number of correct classifications.