

# **COPING WITH THE DEMANDS OF THE 6TH AMENDMENT**

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**Anthony C. Dweck**

**Research Director**

**Peter Black Toiletries, Cradle Bridge, Mortimer Street,**

**Trowbridge, Wiltshire BA14 8BB**

## **Introduction**

The 6th. amendment requires that every company holds a dossier or product information package on all of the ingredients in their formulae. It also requires that all claims are substantiated, and that the product is passed as safe by a qualified person.

## **The Hardware**

The first major step is to have a good fast computer with plenty of hard disc space. A "486 DX, 66Mhz" with plenty of RAM (say 16 MBytes), 250 KBytes of cache memory, plenty of hard disc space (at least 500 MBytes) and suitable software.

## **The Software**

The largest hurdle is deciding on the software and also on the environment in which it is going to operate, though very often the Information Technology Department make those decisions for you.

It is not advised to use an inter-relational data base to store information, because it is often difficult to print it out as a coherent text file that can be manipulated at a later date. The use of any software that relies on 'keywords' is also to be avoided, since this will also create the problem of deciding which word is a keyword. It can be hard to back-track on earlier data to add new keywords.

Ideally, most of us would be happiest reading a text file, because that is the normal way in which information is received. It is a document containing a series of facts held in sentences and paragraphs, with headings and appendices attached with additional information. It is quite usual to want to add additional comments to this document, or merge it with a subsequent document that updates that information.

This is the way in which a word processor or spreadsheet presents information, namely in a logical and sequential manner. To handle information for publication to third parties one must have software to run on the computer and the best word processing package **used to be** Word Perfect, with the best spreadsheet Lotus 123.

The two packages both ran under DOS, and the best way to manipulate the information was with Lotus Magellan (cost £90). This package allowed one to manipulate data; move, copy and delete files and directories, and cut and paste text into new files.

More important, one could run through a long list of files in a given directory and read them directly regardless of which programme they were written in, because Magellan had "viewers". In other words, one could read any file without launching into the software on which it was written. It also allowed files to be indexed and searched, this search being based on whatever group of files that were included in the set.

However, like all good things, Windows came along, and Lotus did not continue to support Magellan, and so Magellan does not run under Windows. It will still "read" Word for Windows files as text files, but Excel appears as a total mystery of gobbledygook! Not at all satisfactory to the committed Windows user.

There are alternative programmes "Eclipse Find" is one alternative, and there is a piece of Shareware called "WinGrep", neither match the absolute brilliance of Magellan.

### **Organisation**

Plan and have a vision of the directory structure. More systems fall apart through poor housekeeping and not knowing where to find a file than any other reason. Learn how to manipulate files and directories. Keep the system logical, other people may need to use it! Keep an index file, which can be updated, to show where all the files are stored.

### **Collect the data**

Remember the magic word "JIJO" or junk in junk out. One only gets out what one puts in.

The data can come from a number of sources.

### **Raw material suppliers**

The raw material suppliers are still bombarding us with reams of paper, all of which had to be typed, all of which was word processed, and so should be available on a floppy disc. Join the fight to rid the world of paper, save the environment, and insist that suppliers provide their catalogues and data on disc. It will save endless typing and the text or data can be incorporated directly into the information pack.

### **Do-it-yourself**

This may well be the most assured source of data at the present time. Set up your own library of those books which you find useful, such as the British Pharmacopoeia,

Merck, The British Herbal Pharmacopoeia, Harry's Cosmetic Materials etc. My own library consists of some 250 herbals and books on medicinal plants for forming just one section of the data base.

## **CD-ROM**

This is an excellent source of data, and there are numerous discs available for example the Martindale Extra Pharmacopoeia. However, it might be difficult to combine your data base with those of the CD-ROM, so that a multi-search becomes necessary to check out a material. Many CD-ROMS have a cut and paste facility, so that it is possible to copy text across into your own file. This is perfectly legal, provided you acknowledge copyright and intellectual rights to the original author and do not copy the whole source of information. Always change a few words and sentences to alter the original work, in order to avoid infringement.

## **Modem links**

The computer can converse with a number of outside data bases, or on-line data bases. These include Medline and Toxline, but there is also the exciting Internet system, which has access into a number of interesting Universities and places where good data is available.

There is usually a charge for these services, apart from the cost of the phone call, which can take ages, especially if you get lost or side-tracked in the system!

## **Networking**

It is not always what you know, but who you know! A network of colleagues exchanging data and information can be a very quick way of obtaining new data and for everyone in the syndicate to establish large amounts of data in their specialist areas.

If information has to be paid for, then make sure it is supplied on disc. Do not let the toxicologist think that he can just say "OK" and write a covering note, get him to prove it with facts and figures, LD<sub>50</sub> values, skin irritation data etc.

## **Information recording**

The information recorded is a matter of choice, but toxicological data, benefits backed up by clinical or instrumental testing are a good place to start.

In the case of plant data, always refer to the plant by Linnean name to avoid possible confusion, always record both the positive and negative results. Some authors can be very negative (out on a limb) when compared to other respected sources. Make it clear which part of the plant is used, whether it is the oil or the extract or the infusion etc., etc.

The more references that are available, the better the judgement that can be made for its safety. Always try and find the dosage level and strengths used. Record the

chemicals present, because these substances may be present in other plants and so enable a comparison to be made on potential toxicity/safety.

Include addresses and telephone numbers, reference book lists, all the cosmetic legislation, trade names, CI numbers, useful information. Form an index that incorporates all of these facts.

### **Using the data base**

After much input of data the system will start to become useful. It seems that the information needs to reach a critical mass before it really starts to show benefits. The data base used by Peter Black is now 25 MBytes in size, contains 2,500 files and took nearly TEN years to compile. Do not be depressed, many of those years were B.C. (before computers) and an increasing number of sources are going computerate.

The data base can now be used for TWO functions:-

1. As a research tool, for example, say we wanted to find a moisturiser. We could search the word moisturiser and every document that mentioned moisturiser would be highlighted as a file. These can then be scanned and a suitable moisturiser chosen.

If you have included the CTPA European inventory in your data, then you will be able to read the CAS number, EINECS number and INCI name as well. It will also be likely to confirm its use as a moisturiser, which would be reassuring.

It may be that you want to include a particular supplier, in which case include his name as an "and" statement in the search criteria, and only his products will appear.

2. As a verification of legal status. We have the whole of the EEC and British regulations in a directory called "legal". We also have a synopsis of the CTPA newsletter, which records any doubts or impending legislation issues in a directory called "CTPA". We also have individual files for each raw material that the company uses, a hotchpotch of papers, toxicological data, legal status, benefits, or disadvantages.

Thus if we searched "Hydroquinone" we would find the legal file, the CTPA newsletter mentions, a separate file on all that we know on hydroquinone, including references from Merck, Martindale, various pharmacopoeias. We could then determine whether or not we wanted to use the material or not. Probably not!

3. To compile the technical information pack. Nothing simpler.

Create a directory called 'formula', copy the formula from the chemist's electronic note book onto the floppy disc. If this is a range of similar formulae, then copy them by laboratory book number.

Call up all the files in the synthetic and natural directories, and go through the formula(e) 'tagging' the required files as one goes down the list. Insert floppy disc

into computer, copy all files across onto the disc, dividing materials into 'excipients' and 'actives' directories.

Pick up the pack copy, and scan the new floppy for the key words used in that text. If the exact words have not been used, then search for synonyms or alter the wording to fit the data.

Next, change directory to the one where the physical test results are kept and copy these onto the floppy disc, place files in directory called 'testing'. Copy the microbiologist challenge test results into file called 'micro' also including any other results, such as TVC from first production etc.

Finally, create a directory called 'external' testing and copy the report from the toxicologist, dermatologist on to the disc.

This is your information package. You do not have to collate it in this way, the law only says that you have to be able to compile such a package of information. One floppy disc can hold as much as TWO lever arch files full of data. Thus for each product you keep one floppy disc, which can be filed for the six years normally advocated.

### **Conclusion**

Designing a data base is easy, the only down-side is the time and commitment it takes to pull all that information together. With more and more companies being prepared to let their catalogues be released on floppy disc, it has become a great deal easier and faster to accumulate data.

A good data base is worth its weight in gold. It is a valuable treasure house of all the things so easily forgotten, a means of collating and reading through thousands of pages of information at the press of a button.

The 6th. Amendment a problem? Certainly not - it is a great opportunity!

Anthony C. Dweck  
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