

Natural matrix RMs need to be “classified for supply”

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Producers of RMs, even natural products, must comply with the GB CHIP Regulations and the EC Dangerous Substances and Dangerous Preparations Directives. A recent review of these documents and the EU Manual of Decisions, confirmed a suspicion that natural products are not subject to any exemptions. So if the producer, supplier or user knows that the material they are handling contains any component that would result in classification as hazardous, then that product must be properly classified and labelled. Also, known impurities, as well as intentionally added components, need to be taken into account when classifying a substance.

Research carried out for the DTI in 2005 (www.impub.co.uk/dti/) showed 33 European Chemical Control Regulations include RMs in their scope and the report went on to conclude “The overall picture is bleak. Full and effective enforcement of all 33 regulations would effectively remove most RM sources and many RM products from the European marketplace”.

The main areas of concern for RM producers—and this includes every laboratory that produces RMs in-house for in-house, non-commercial consumption—are:

Chemical Supply: Dangerous Substances Directive 67/548/EC; 1992/32/EEC; The Dangerous Preparations Directive 1999/45/EC; The Restrictions on Marketing and Use Directives 76/769/EEC & 2001/41/EC; and The Safety Data Sheet Directive 91/155/EEC

Storage: The “Seveso II” Directive 96/82/EC

Prior Informed Consent: Regulation EC 304/2003 & 775/2004

Ozone Depleting Agents: Regulations EC 2037, 2038 & 2039/2000

In vitro Diagnostics: Directives 90/385/EC, 93/42/EC 98/79/EC, 2000/70/EC, 2001/104/EC

REACH: Draft Regulation 2005

GHS: EU Consultation 2006 and draft Regulation 2007

Plant Pathogens: Directive 95/55

Endangered Species: CITES UN Convention

Child Health: SCALE / CEHAPE

The real problem is that these 33 regulations were drafted with little concern for the consequences of implementation: there are no “small quantity” exclusions, so the rules apply equally to 100 mg as 1000 tonnes. In the UK the Health and Safety Executive and other enforcement bodies generally take a pragmatic view and do not generally enforce the rules when small quantities of material, packaged for use as RMs concerned. But there is no escaping the fact that most European producers of RMs do not fully comply with every aspect of the regulations and directives listed above, let alone the full list of 33 mentioned in the DTI review.

The EU has recently lowered the bar even further reducing the level of many common environmental pollutants and naturally occurring elements at which a product must be considered to be “dangerous for supply”. The new levels, which come into force in the first part of 2007, go down as far as 0.25ppm for some pesticides, levels which are found in some natural waters and soils! Slightly higher levels are allowed for many elements found in industrial and domestic waste and in certain natural minerals, for example:

Copper compounds, Inorganic mercury compounds, Lead ions, Nickel compounds

Selenium compounds, Silver compounds and Zinc compounds:

2500 ppm

Arsenic ions, Beryllium compounds, Cadmium ions, Chromium compounds and

Cyanides: **1000 ppm**

Diethylmercury, Dimethylmercury, Lead alkyls, Organomercury compounds, Triethyltin compounds and Trimethyltin compounds: **500 ppm**

Cadmium chloride, Cadmium fluoride, Cadmium sulphate and Cobalt ions: **100 ppm**

In the organic sector most common pesticides are limited at 25 and 50 ppm, but the limits go down to 0.25ppm for Chlorpyrifos, Chlorpyrifos-methyl Ethion and mevinphos.

The implications of these new low levels are significant: once it is known that any sample or material contains any of the listed substances subject to the lower limits it must be treated as hazardous. So harmless analytical samples once analysed will join the soil RMs that now have to be labelled as hazardous!

The result is higher cost: material now disposed of as non-hazardous will become hazardous waste, with greatly increased cost of disposal. RM producers will have to review their product ranges and re-label, or add additional labelling and issue new Material Safety Data Sheets, adding to their costs.

Finally, in the UK, it seems the levels at which the EA requires soils are decontaminated have not yet changed, so could we end up with the possibility that a soil which is considered acceptably safe for building or other use in the ground, once dug up must be labelled hazardous? This seems surreal, but in the world of EU chemical regulation it is clear that anything is becoming possible.