

MEMORANDUM

To: Caroline Braibant **File:** 088000/0034
From: Elena Kostadinova **cc:** Scott Megregian
Subject: Exemption from Registration **Date:** 12 December 2007
of Substances which occur in
nature, if not chemically
modified

The European Precious Metals Federation (EPMF) has received a copy of a legal opinion provided by Houston Consulting Europe to UBS dated October 2007. We have been asked to evaluate this opinion and in particular provide an independent assessment of whether precious metals such as gold would be exempt from registration under Annex V of the REACH Regulation.

We have reviewed the opinion of Houston Consulting Europe. The opinion (i) does not assess whether the precious metals fit within the definition of “substances occurring in nature”, nor (ii) does it explain why they have concluded that the ores containing precious metals do not undergo chemical processing to produce the substances, such as gold, silver, etc. Hence we are not in a position to assess their analysis and must instead analyse the issue de novo.

The exemptions listed in Annex V of the REACH Regulation are subject to considerable controversy and a degree of continuing uncertainty. Our analysis is based on an evaluation of the REACH Regulation, the REACH Implementation Projects, and consideration of interpretation work undertaken by other trade bodies, such as Eurometaux. Based on this review, we believe that most, if not all, precious metals such as gold, platinum, silver, etc. are subject to registration if manufactured in the EU or imported into the EU in quantities of one or more tonnes per year. Indeed, this is the position being taken by most other relevant metals. (Please note that this interpretation may need to be revisited if Annex V is revised or if further guidance is provided by the European Commission.)

1. Exemption

According to the Guidance for identification and naming of substances under REACH, substances, as defined in the REACH Regulation, include substances chemically derived or isolated from naturally occurring materials, which may comprise a single element or molecule (e.g. pure metals or certain minerals) or several constituents (e.g. essential oils, metal mattes).¹ In its Questions and Answers on REACH, the Commission explicitly notes that metals are substances under the REACH Regulation. Metals have been considered as chemical substances under EU legislation since 1967, and they are recognised as such internationally (for example under the UN Globally Harmonised System for Classification and Labelling).² The REACH Regulation, however, provides for certain limited exemptions

from registration of such substances.

Article 2(7)(b) exempts from registration substances covered by Annex V, “as registration is deemed inappropriate or unnecessary for these substances and their exemption [from registration] does not prejudice the objectives of the [REACH Regulation]”. Paragraphs 7 and 8 of Annex V set forth the relevant exemptions:

7. The following substances which occur in nature, if they are not chemically modified: minerals, ores, ore concentrates ...

8. Substances, occurring in nature other than those listed under paragraph 7, if they are not chemically modified, unless they meet the criteria for classification as dangerous...

2. Conditions

While minerals, ores and ore concentrates are specifically included in paragraph 7, metals are not. If exempt, metals would have to fit within the exemption set forth in paragraph 8. Three main conditions should be satisfied for the exemption to apply: (i) the substance should occur in nature, (ii) the substance which occurs in nature should not be chemically modified and (iii) this substance should not be classified as dangerous.

As we understand, there is no data that the primary precious metals (for example gold, silver, platinum) are dangerous, we limit our analysis to the first two conditions. (If there is such data showing that certain precious metals are dangerous substances, then this would clearly take them outside of the exemption.)

2.1 (i) The substance should occur in nature

The REACH Regulation provides for a definition of substances which occur in nature in Article 3(39):

means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means.

The definition of a substance which occurs in nature limits the application of the exemption to substances that are not processed or have undergone a physical transformation only such as crushing or flotation. Hence, precious metals could only qualify for this exemption if unprocessed or if their production process is limited to one of the above forms of processing.

2.2 (ii) The substance which occurs in nature should not be chemically modified

The exemption for substances which occur in nature is further clarified so as to apply only if the substance is not chemically modified. The requirement that such substances cannot be chemically modified restricts the application of the exemption. Pursuant to Article 3(40) of the REACH Regulation, “not chemically modified”:

means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or

treatment, or a physical mineralogical transformation, for instance to remove impurities.

It follows from the definition that the substance is not chemically modified if its chemical structure remains the same. While the definition allows for some chemical treatment, to eliminate impurities, the chemical nature of the substance must not change.

3. Interpretation and application of the exemption

The exemption applies only to substances which occur in nature if they are not chemically modified. Substances occur in nature if they are used unprocessed or were subject to certain physical transformation listed in the definition. In addition any processes or transformations of the substance should not lead to a change in its chemical structure. The second definition suggests that the substances that occur in nature may be subject to chemical process or treatment only to the extent that impurities are removed. Any process that lead to extraction of metal from the ore or concentrate would appear to fall outside the exemption. It should be noted that the exemption in Annex V of the REACH Regulation would not exclude a situation where the impurities are treated chemically and then separated from the substance by a physical process. In such case, the substance still would be covered by the exemption.

Our understanding is that, in the vast majority of cases, the production of metallic gold produced from high or low grade ore includes chemical treatment and leads to chemical modification. According to the American National Mining Association³ ore containing gold is subject to grinding and/or crushing. Depending on the production process involved the processed ore is then subject to roasting and/or cyanide leaching to extract the gold from the ore. This roasting or leaching occur for the pupose of metal extraction and not simply to remove impurities. Such process involves chemical treatment and leads to a chemical modification of the ore occurring in nature.

If some gold would be produced in pure form only through mechanical means such as crushing, flotation and drying, then gold produced by such means could fall under the exemption from registration under Annex V of the REACH Regulation and manufacturers using this process could claim exemption from registration. However, gold produced using chemical processing such as through roasting or leaching would require registration. (Please note that each company would need to take a decision to apply or not to apply the exemption under Annex V of the REACH Regulation based on its own production process.)

We have used gold as an example and have not examined the production process for silver, platinum, osmium, palladium, rhodium and ruthenium. If the extraction of these substances requires a chemical process, these substances would have to be registered when manufactured in the EU or imported into the EU in volumes of one or more tonnes per year. We can evaluate each of them individually, if this would be helpful. However, we would need more information on the specific production process used in each case.

The analysis above is further supported by draft guidance document being prepared by Eurometaux. This guidance document includes a table of processes that would normally qualify as chemical modification:

Process/Step	Chemically modified?	
Optical/Mechanised Sorting		No
Magnetic/Electrostatic Separation		No
Gravity or Dense Medium Separation		No
Preferential Crushing, Grinding or Milling		No
Screening, Hydrocycloning or Classification		No

Agglomeration or Froth Flotation		No
Thickening & Filtration		No
Drying		No
Leaching/Washing Processes to remove impurities		No
Pelletising of magnetite ore		No
Leaching Processes to extract the value mineral	Yes	
Ion-exchange, Solvent Extraction or Electro-winning	Yes	
Pressure Digestion in aqueous NaOH	Yes	
Sintering, Roasting, Smelting & Converting	Yes	
Calcination	Yes	
Precipitation and gas precipitation	Yes	
High Temperature or Electro-refining	Yes	

The consensus of the Eurometaux experts is also that both roasting and leaching for metal extraction could constitute chemical modification.

4. Conclusion

It is our understanding that the exemption of Annex V paragraphs 7 and 8 would apply to substance which occur in nature if they are unprocessed, have been subject to a physical transformation or a chemical process or treatment to remove impurities if this process does not change the chemical characteristics of the substance. We believe that the definition of chemically modified substance in this context should be interpreted broadly. This means that the substance that occurs in nature may be subject to a physical mineralogical transformation or a chemical process or treatment to remove impurities but not to a chemical process or treatment to remove the metal from the ore or concentrate to derive a pure metal. Based on the above, precious metals such as gold would be subject to registration and are unlikely to be covered by Annex V of the REACH Regulation. Depending on the production process, the same may apply to the other precious metals.

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- ¹ Guidance for identification and naming of substances under REACH, p. 8
http://ecb.jrc.it/documents/REACH/RIP_FINAL_REPORTS/RIP_3.10_SUBSTANCE_IDENTITY/substance_id_en.pdf
 - ² Questions and Answers on REACH, July 2007, p. 7, section 2.1.14
http://ecb.jrc.it/documents/REACH/REACH_PROPOSAL/Questions_and_Answers_on_REACH.pdf
 - ³ http://www.nma.org/technology/gold_production.asp