



71 Four Valley Drive
Concord, Ontario L4K 4V8
Canada

Response to 1st Questionnaire (Clarification Questionnaire)

Date: 2017-09-11
Reference:

Oeko-Institut e.V.

Subject: Exemption for “Lead in solder used to make electrical connections to vacuum boards used in Mass Spectrometers. Boards designed to be used periodically under low pressure“, requested for five years

Questions and Answers

Q1. Sciex is one manufacturer of mass spectrometers. Please provide a list of other manufacturers of mass spectrometers in the EU and outside.

A1. Here is a list of the major global manufacturers of mass spectrometers known to AB Sciex.

Agilent	www.agilent.com
Applied Biosystems	www.appliedbiosystems.com
Bruker	www.bruker.com
Hitachi High Technologies	www.hitachi-hita.com
IONICON	www.ionicon.com
JEOL	www.jeol.com
LECO	www.leco.com
PerkinElmer	www.perkinelmer.com
Shimadzu	www.shimadzu.com
Thermo Fisher Scientific	www.thermoscientific.com
Waters	www.waters.com

Q2. Sciex estimates the total amount of Lead (Pb) entering the EU market annually (in all instruments) between 1,342 g to 2,684 g (1.342 kg to 2.684 kg) depending on the instrument and the number of contacts per PCB for which the exemption is requested.

Q2a. Do these figures (1.3 to 2.7 kg per year) refer to AB Sciex' products only, or to all mass spectrometers assuming that they would use the requested exemption?

A2a. The amount was intended to represent AB SCIEX products. The total amount of Lead (Pb) entering the EU market annually from AB SCIEX products has been recalculated since the initial application. The total amount of Lead (Pb) is 26g based on current shipping products and volumes.



Q2b. Please provide a rough calculation to substantiate the above figures if possible for the total amount of lead that would be used by all manufacturers of mass spectrometers under the requested exemption.

A2b. Such information is not available to AB Sciex.

Q3. Directive 2011/65/EU (RoHS 2) was enacted in 2011. Please explain which steps Sciex undertook since 2011 to achieve RoHS compliance.

A3. Alternative solutions are under investigation including different interconnect technologies and different solder types.

Q4. In your suggested exemption wording, the PWB on the one hand shall be exposed to vacuum, on the other periodically to low pressure.

Q4a. Please specify what you mean with "vacuum" and "low pressure".

A4a. There are a variety of vacuum regions in our mass spectrometer instruments. The vacuum regions are where the properties of the eutectic tin-lead solder are important for maintaining low leak rates. AB Sciex considers vacuum to be 0 psia.

Q4b. Why has the PWB to be exposed to low pressure/vacuum? Can design changes avoid this exposure so that the use of lead becomes obsolete?

A4b. The PWB's are serving the function of an electrical feedthrough from atmospheric pressure to vacuum pressure. The exposure to vacuum is inherent in the function.

Q4c. Would this exemption be required for all mass spectrometers, or only for specific types?

A4c. It is required for certain types of mass spectrometers.

Q4d. In case it is only required for specific types of mass spectrometers, please explain which ones and describe their functionality/performance features.

A4d. The new families of mass spectrometers use the PWB for electrical feedthrough from atmospheric pressure to vacuum pressure. Their design originated pre-RoHS requirements.

Q4e. In case this exemption would only be required for specific types of mass spectrometers, please explain the specific properties and features of these devices compared to others which do not need this exemption, and why these features cannot be achieved otherwise (without the exemption).

A4e. The properties relate to the specific interconnections being handled by each PWB. Generally, the instruments are able to achieve better signal integrity and interconnection density using PWB's as compared to more conventional welded or potted feedthroughs.

Q5. As part of the evaluation, socio-economic impacts shall also be compiled and evaluated. For this purpose, please provide details in respect of the following:

Q5a. Volume of electrical and electronic equipment (EEE) concerned, which is placed on the EU market annually;

A5a. The list is considered proprietary information.

Q5b. Please estimate possible impacts on employment in total, in the EU and outside the EU, should the exemption not be granted. Please detail the main sectors for which impacts are expected, i.e. manufacturers, supply chain, retail, etc.

A5b. The estimate is considered proprietary information.

Q5c. Please provide a list of manufacturers of your EEE for which you apply for the exemption in and outside the EU (see question 1);

A5c. AB Sciex is the Manufacturer of record.

Q5d. Please quantify additional costs (money expenditure) through substitution of the restricted substance – or replacement of the EEE by other, RoHS-compliant EEE if feasible - divided into sectors (private, industry, public) if the exemption request is granted vs. its rejection;

A5d. Granting the exemption would permit:

Public:

- Assurance of Food Quality and Safety - testing of Pesticide, Food Authenticity, Allergen, Antibiotic, as well as Ingredient analysis and Unknown substances screening.
- Environmental exposure to chemical hazards - testing of environmental contaminants, drinking water and wastewater testing, environmental fate analysis and soil and biota testing.
- Drug Discovery and Health Research - used to detect and quantify trace amounts of analytes in samples.
- Solutions for Forensic toxicology.

Industry:

- Continuation of routine testing of food quality and safety along with continuation of environmental analysis.
- Continued health research identifying key genes, proteins, lipids and metabolites to further understand health and disease in life sciences.
- Continued forensics toxicology analysis.

Private:

- Continued employment, financial remuneration from the sale and support of the instruments and within the industries such equipment supports.



Rejection of the exemption will eliminate the subject products from the market, with the following impact:

Public:

- Reduced food quality and safety, greater potential for exposure to chemical hazards, slower drug discovery and health research.
- The benefits and return to the public from using these instruments surpass any individual financial impact.

Industry:

- The environmental monitoring, food safety, pharmaceutical research and forensics industries will face financial impacts represented in loss of revenue; furthermore there will be unforeseen expenditure related to disruption caused by the unavailability of these instruments.

Supply chain:

- Loss of revenues and growth opportunities in the EU and abroad. This will be reflected directly on vendor employment headcount and operations.

Private:

- Loss of revenue, employment, operations delays and customer satisfaction concerns.

Q5e. Is there any generation of additional waste to be expected if the exemption is granted vs. its rejection;

A5e. There is no additional waste generated if the exemption is granted. Material and assembly scrap is possible if the exemption is not granted.