29 June 2012

To Commissioners:
Antonio Tajani
Vice-President of the European Commission
Commissioner for Industry and Entrepreneurship
B-1049 Brussels
Belgium

Janez Potocnik
Commissioner for Environment
B-1049 Brussels
Belgium

Dear Commissioners,

Re: **Joint Letter of Concern to the European Commission on ECHA's recommendation to list five cobalt salts on REACH Annex XIV**

We are writing to express our deep concern and to highlight the significant impact ECHA's recommendation of 21 December 2011 to place five cobalt salts on the REACH Annex XIV list of substances subject to Authorisation (hereafter the 'Recommendation') will have on European downstream user industries of these critically important substances. If the Recommendation is endorsed by the European Commission as presented by ECHA, it will result in an effective ban on the use of these substances by European businesses of all sizes. More importantly, it will have an immediate and damaging effect on a number of key manufacturing, research and innovation sectors, particularly upon SMEs. Those sectors which will be affected include healthcare and industrial biotechnology, diagnostics and biopharmaceuticals, surface engineering, and renewable energy.[1]

We believe Annex XIV listing will result in an effective ban on the use of these five cobalt salts because the cost, time and regulatory uncertainty involved in applying to ECHA for Authorisation as part of the formal REACH process is disproportionately heavy compared to the overall value of cobalt salts. In some cases, e.g. in fermentation or catalytic processes, the cobalt salts are used in such minute quantities that there is no assurance that either the European based producers or suppliers of these five cobalt salts will bear the cost of Authorisation so specific uses can be sanctioned. The volumes are just too low to make it cost effective thus placing the cost and burden of Authorisation squarely on the ultimate users, which are predominantly SMEs in our industries. Even in cases where the use is not subject to Authorisation, e.g. intermediate use, there is concern that the cost burden associated with uses subject to Authorisation will threaten the overall availability of these five cobalt salts in the European market.

We further believe that sanctioning the Recommendation as presented by ECHA will have an immediate and long term impact on the industrial supply chain, whilst putting European industry at a severe trade and competitive disadvantage to imports from third countries not subject to this measure. Cobalt salts are used as process chemicals and are not present in the final product, meaning that imports from third countries would not be subject to the same costly Authorisation requirements as European industry. Indeed, the risks associated with having to secure an Authorisation, and the limited period of use such an Authorisation provides, will deter investment decisions and contradict other measures instituted by the Commission to prevent trade distortions (such as anti-dumping

[1] For more information on impact on specific sectors see Appendix 1 attached.

measures already in place in the polyester sector). . In cases where cobalt salts have no alternatives, production would simply be relocated to non-EU countries. This is in contradiction with the aim of REACH to foster growth and competiveness.

Finally, the simple act of listing the cobalt salts on Annex XIV would adversely affect Europe's leadership position in innovation, demonstrate a lack of regulatory efficiency for its incoherence with other EU policies such as encouraging ways to combat climate change, and stand in direct contrast to the EU's decision declaring cobalt a critical raw material essential for European jobs and growth.

Several sectors provide examples of significant sectors where removal of cobalt would lead to major issues, including the lack of availability of medicines and diagnostic technologies for treatment in the EU, the very significantly increased energy inefficiencies in manufacturing operations in general (and in particular in the Polyester Monomers sector), or the extinction of EU participation in some of these sectors.

Given the potential for significant impact on innovation, competitiveness and particularly on the supply of materials to SME's across several key industry sectors, we request that the European Commission conduct an appropriate impact assessment before any decision is made concerning the Recommendation. This impact assessment should consider the following:

- Is the proposed measure appropriate, i.e. is Authorisation the most efficient regulatory measure to ensure safe use of the cobalt salts?
- Have all the available risk management measures already in place at the EU and Member State level been properly considered?
- Is the proposed measure proportionate? Will the controls on the substances provided by the costly process of applying for Authorisation outweigh the significant impact on European industry with regard to investment and jobs? Will it significantly improve the protection of human health and the environment?
- Is the proposed measure in-line with other EU policies and initiatives to promote innovation and sustainability?

An impact assessment, done in accordance with the Commission's *Better Regulations Initiative* and the *Impact Assessment Guidelines*, will contribute to a better understanding of the implications of ECHA's Recommendation. Industry associations, including those comprised of the most affected SMEs, are prepared to participate actively and immediately in any process or discussions that would contribute to an informed and evidence-based decision about the proposed Recommendation.

We support the objectives of the REACH Regulation (Article 1(1) of 1907/2006/EC) *"to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation."* However, we would like to stress the necessity of reaching a decision which also supports innovation and competitiveness and that is proportionate and practical in the circumstances.

We believe conducting an impact assessment on the Recommendation is the best way to achieve this goal. With the support of industry stakeholders and others such an impact assessment can be done expeditiously and without circumventing the established REACH process. Indeed, we feel that this assessment will strengthen the REACH process by giving proper attention to the issues raised by the Recommendation. Therefore, we are asking the Commission to conduct such an assessment in order to ensure that the REACH decision making process is robust, transparent, accountable, and meets simultaneously the objectives of the REACH regulation and the goals of the Commission's own *Better Regulation Initiative*.

Thank you for your attention to this request.

Undersigned:

Lewiatan (Polish Confederation of Private Employers)

ECMA (European Catalysts Manufacturers Association

CPME (Committee of PET Manufacturers in Europe)

CETS (European Committee for Surface Treatments)

Lithuanian Business Association

EuropaBio (European Association for Bio-industries)

EDMA (European Diagnostics Manufacturers Association)

POLISH CONFEDERATION OF PRIVATE EMPLOYERS LEWIATAN

Lech Pilawski, Director General, **Lewiatan**

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Stephen A. Short, Chairman, **CPME**

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Berthold Seßler, President, **CETS**

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Mr Gediminas Rainys, Director General, **Lithuanian Confederation of Industrialists LPK**

EUROPABIO™ The European Association for Bioindustries

Nathalie Moll, Secretary General, **EuropaBio**

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edma DIAGNOSTICS FOR HEALTH

Jesus Rueda Rodriguez, Dir. Regulatory Affairs, **EDMA**

Appendix 1

Impact of ECHA Recommendation on Downstream Users of Cobalt Salts[1]

Information from the Cobalt Manufacturing Industry and its Downstream Users on the impact of ECHA's Recommendation to place on Annex XIV
Five cobalt salts (cobalt sulphate, -diacetate, -carbonate, -dinitrate, -dichloride)

Need for an Impact Assessment

Threat to Competitiveness: The disproportionately high costs of applying for Authorisation relative to the low volume of cobalt salts used will encourage a shift of production outside the EU. Simultaneously, Europe will increase its **dependency on external supplies cobalt salts despite the fact that cobalt is recognized as** a critical raw material by the EU. Only European companies will be affected by this, creating an artificial distortion of the market while posing a significant **threat to the competitiveness** of the EU.

Risks to Small and Medium Enterprises (SMEs): The risk of being listed on Annex XIV is particularly significant to SMEs. This is due primarily to the distortive effect Authorisation will have on users further downstream. The low tonnages of cobalt salts used in the diagnostics, biopharmaceutical and surface treatment sectors means the SME end users will have to bear the risks and costs of Authorisation in order to continue their use).

Innovation will be undermined: In the pharmaceutical and biotechnology sectors in particular, discovery and research projects are usually contracted out to SMEs by large companies. The Recommendation failed to consider the role cobalt salts play in Product and Process-Orientated Research and Development (PPORD). As result, the only way to use these cobalt salts is if the SMEs in this sector secure the necessary Authorisation(s) (as they would likely be using more than one substance under Authorisation).

Disproportional and impractical: There is little additional protection of human health and the environment derived from listing these five cobalt salts on Annex XIV and requiring an Authorisation to allow their use. The five cobalt salts are already used in highly controlled situations and subject to extensive regulations at both the EU and member State level. The cost and risk associated with Authorisation are neither a proportionate or practical response to the risks these five cobalt salts represent.

Industries Affected by the Recommendation

Polyester industry

- Cobalt diacetate is an essential intermediary used in the manufacture of PTA, IPA and DMT.
- There are only nine manufacturing locations in seven member states in the EU.
- 8.7 Million tonnes of polyester are produced, equivalent to €9 billion pa added value in the EU.

[1] This note focuses mainly on the uses that are currently considered as in-scope and have been recommended for Authorisation by ECHA ('the Recommendation' hereafter). Information on the socio-economic impact of the Recommendation is not available in several sectors, given the complexity of the supply chain.

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- 2,700 direct employees are concerned.
- 8% of total global PTA/IPA/DMT capacity is based in the EU. This means 92% of global PTA/IPA/DMT production is not subject to REACH and therefore will not be impacted by the Recommendation.

Surface treatment industry:

Overall (EU): €1.6 billion of added value generated EU-wide by companies involved in electrochemical galvanising (or passivation) would be directly affected (~80% of the five cobalt salts volume used in surface treatments is used for galvanisation. ~20% of the volume of the five cobalt salts is used for plating.
500 sites in Poland (mainly SMEs), almost all disappeared in Spain.

Number of sites for plating and galvanisation using cobalt salts across Europe: 2500, of which 1000 are in Italy, mostly SMEs with on average 10 workers (but a few large ones of ~300 employees), very few in Poland, almost none in Spain. For France, no information is as yet available, but the sector has huge importance.

Two of the main sectors are the *automobile and the aerospace* industries:

- *Automobile industry:* Inappropriate prioritisation of cobalt salts at this time would risk ~20,000 jobs in the EU that are directly in the zinc plating industry, but also over 1,000,000 jobs in all industries which are dependent on reliable high quality parts, mostly used for security components (electronic circuits, and fixings).
- *Aerospace industry:* Only 3 tpa of cobalt sulphate (out of the 115 tpa cobalt sulphate used in the EU for surface treatment) are used for the aerospace industry. This is by suppliers of core security components of specially surface coated engine parts (e.g. engine blades) to the aerospace industry. The aerospace sector is very concerned that a) long-term (over the 20-year lifetime of the engine) supply will be disrupted, and b) the application date should be deferred by several years to enable research of alternatives and validation testing of the parts.

Pharmaceutical Industry

- This use is important for medicines against major diseases (cancer, diabetes, Crohn's disease, rheumatoid arthritis, …).
- Cobalt dichloride is mainly used (but so are cobalt sulphate and diacetate, and some cobalt carbonate or dinitrate).
- Cobalt dichloride is not used as an Active Pharmaceutical Ingredient (API) and is therefore not covered by the Medicinal Products for Human and Veterinary Use Regulation.
- It is indispensable as an essential micronutrient for cell cultures in fermentation processes for industrial biomedical and laboratory operations.
- Because of its biological essentiality, it cannot be replaced by another element.
- In the UK Medical Biotechnology Industry alone there are 945 companies of which 325 are directly involved in therapeutic development and manufacture. The combined turnover is £3.4bn with total number of employees 23,000, of which 98% of companies have <250 employees[2].

[2] HM Government (BIS, UKTI, DH) Report Strength and opportunity 2011 – published December 2011

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Diagnostics

In vitro diagnostics (IVD) provide diagnostic information by examination of a specimen derived from the human body. Approximately 64% of medical decisions are reached following a diagnostic test (e.g. diabetes, pregnancy…). Over 90% of the European IVD industry is made up of SMEs . Cobalt dichloride is used as an essential nutrient in key fermentation systems to provide various biological substances needed in the production and development of IVDs. Without the cobalt ion present in the fermentation mixture, cell cultures will not grow. The substance is used in laboratories and receives a high level of protection which is typical for the IVD industry and the quality requirements to produce and finish the products. The industry uses less than 100 kg of *cobalt dichloride* per year (rough estimate). The concentration of Cobalt Dichloride in stock solution for fermentation processes usually ranges between 4 to 25 g/L (0.4%-2.5%). The concentration of Cobalt salts in fermentation solutions usually is well below 0.01%.

Biotechnology

Industrial biotechnological and laboratory operations commonly use Cobalt Dichloride as trace element in a culture media. Catalytic elements such as the cobalt ion are commonly and safely used and are essential to activate fermentation and enzyme processes related to human and animal health.

The uses of Cobalt Dichloride in the biotechnological industry concern only a small percentage of the production and use in Europe (<<1%, ECHA 2009, CoRC comments to ECHA publication on 3rd recommendation for prioritization of 14 September 2011).

The concentration of Cobalt Dichloride in stock solution for fermentation processes usually ranges from between 4 to 25 g/L (0.4%-2.5%). The concentration of Cobalt Dichloride in fermentation solutions usually ranges from between 0.05 to 10 mg/L (0.000005%-0.001%). Once the fermentation process is complete, the remaining Cobalt Dichloride, if any, is separated from the end products using separation and purification processes.

Cobalt Dichloride is also added to culturing media to support microbial (a.o.bacterial) growth used in the production of organic biomolecules including therapeutic peptides, vitamins, enzymes for pharmaceuticals, food and feed, antibiotics, single-cell proteins, organic substances, and antibodies. These biomolecules are used as part of medicinal treatments, such as vaccines and are also essential in further transformation steps of biochemicals. Furthermore the biomolecules also play an important role in research and development.

Biogas

Biogas production in the EU is an integral part of many environmental technologies used for the degradation of complex organic materials (such as sewage sludge treatment, bio-waste treatment and energy crops) to produce energy-rich gas, called biogas and a fermentation residue, called ‘digestate’.

Biogas is a methane-based energy carrier widely used for delocalized electricity and heat production (CHP). Treated biogas is also used as a renewable replacement of natural gas. Elemental cobalt is an irreplaceable oligo-element essential to the metabolism of methanogenic bacteria (four cobalt salts are used, excluding cobalt dinitrate).

Biogas is an important renewable energy source within Europe, and its production from agricultural and organic waste is not only encouraged by the **Waste Framework Directive**, but also one of the pillars of the **European bioenergy policy**, embedded in the **National Renewable Energy Action Plans** in all the 27 Member

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States. The current European production is 8,346 thousands of tonnes of oil equivalent per year (Eurobserver, 2009). For example, Germany has targets to replace 6 billion m3 per year of natural gas with treated biogas by 2020.

Biogas production is also an important part of agricultural manure treatment in **sustainable agriculture** by utilizing manure, thus efficiently avoiding ammonia and nitrous oxides emissions which are prone to be emitted from open manure storages. Sustainable agriculture also benefits from the fermentation residue (digestate). The digestate is returned to the agricultural fields, bringing back all the nutrients taken away by the plants and removed during the harvest. The use of digestate efficiently reduces or even avoids the use of artificial fertilizers on the digestate-fertilized fields.[3]

Humidity Indicator cards

This application is important for security component monitoring (precision instruments, braking systems) in military (and also industrial) aerospace, automotive and electronic industries.
Cobalt is the only element allowing precision performance key to these sectors.
The salts are not interchangeable.
One company ensures 90% of the global production, whilst using only a few kilosper year.

EU Animal Feed industry (exempted/out of scope)

All cobalt salts are used, but mainly cobalt carbonate and cobalt sulphate.
There are two distinct uses:

- Use of cobalt dichloride as intermediate for the synthesis of vitamin B12 (cobalamine). This use is not in scope of Authorisation.
- Cobalt salts added to premixes for the feed: use is covered under the Feed Additive Regulation (EC) No 1831/2003. This use should be exempted but ECHA has made no suggestion of it.

In the EU, the turnover for this sector is ~ € 50 billion, producing €150 million tpa of compound feed in ~ 4,000 feed units employing 100,000 persons in rural areas.
Compound feed is an essential input for the 8.5 million EU livestock farmers whose production represents annually €140 billion.

Sectors using cobalt salts as *Intermediate* uses

Although intermediate uses are exempted from the authorisation requirement, in reality, the market for these uses will also be negatively impacted due to the uncertainty of the intermediate status approval; this is even more likely given the current divergences of opinion as to intermediate status for a number of applications and between Member States. As these intermediate uses account for over 80% of the uses, it will affect a considerable portion of the EU market for cobalt salts.

[3] A separate note with more detailed information from this sector is available on request.

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