

A BUSINESS MANAGEMENT SYSTEMS APPROACH TO COMPLIANCE & RISK MANAGEMENT

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EXECUTIVE SUMMARY

In the last ten years, there has been a significant growth in regulation targeting product environmental impacts. Such regulation can be broadly termed Extended Producer Responsibility whereby the manufacturer is made financially and legally responsible for their products environmental impacts during each stage of its lifecycle. Predominantly the areas of focus are on product recyclability, and to minimise the use of substances that are harmful to human health or the environment. In response to this relatively new form of regulation, industry is undergoing a rapid learning curve to develop the necessary frameworks and tools for compliance and risk management that are required to respond.

This report takes a retrospective look at how the automotive industry managed the implementation of part of the European End of Life Vehicles (ELV) Directive, namely the ban on hexavalent chromium in corrosion preventative coatings. This report is based on a number of interviews carried out with members of the UK Automotive REACH Group, and EPR Consultings own experience to provide perspective from a number of actors involved in the process. The contents of this paper were presented at the Denver Aerospace and Defence E2S2 conference in June 2010 by the author.

From this exercise, areas of best practice and lessons learned are derived that can be brought to bear on the current regulatory environment and related business risks. An overview is presented of an integrated business systems approach to managing compliance and risk. Suggestions are made as to how industry can act collectively to manage compliance and risk management throughout their supply chain.

1. LESSONS LEARNED FROM THE PHASE OUT OF CR6+ UNDER THE END OF LIFE VEHICLES (ELV) DIRECTIVE

Background to the ELV Directive & Timetable for phase out of Cr6+ used in Coatings

The ELV Directive was one of the first Producer Responsibility Directives to emerge from the European Union. Adopted by the European Parliament and European Commission in September 2000, it made vehicle manufacturers financially and legally responsible for managing product environmental impacts. In particular:

- The mandate of re-use, recovery and recycling targets for vehicles at end of life
- The ban of four heavy metals: Cadmium, Lead, Mercury and Hexavalent Chromium in new vehicles

The ban on heavy metals in new vehicles came into force in July 2002, and applies at the homogeneous material level from when the vehicle is placed on the market. A number of exemptions for the ban are provided for in applications where there is no technically feasible alternative. The exemptions are listed in the Annex II of the Directive, which is updated every 2-3 years in line with industry progress in finding alternative substances, materials and processes to facilitate the progressive phase out of these substances. This process is overseen at the European Commission level by the Technical Adaptation Committee.

The progress of the phase out of hexavalent chromium under the ELV Directive in corrosion preventative coatings is shown in Table 1 below:

Table 1: ELV Directive Annex II revisions for Hexavalent Chromium used in Corrosion Preventative coatings.

Annex II Version	Exemption	Exemption Expiry Date
1 st Annex II (29/06/2002)	Corrosion preventive coatings	1 st July 2007
2 nd Annex II (30/09/2005)	Corrosion preventive coatings	1 st July 2007
	Corrosion preventive coatings related to bolt and nut assemblies for chassis applications	1 st July 2008
3 rd Annex II (23/08/2008)	As spare parts for vehicles put on the market before 1 July 2007	-
	As spare parts for vehicles put on the market before 1 July 2008	-

NB/ It is important to note that the ban applies to residues of cr6+ remaining unreduced within platings based on hexavalent chromium based processes. The process itself is not banned under the ELV Directive and is controlled by separate Environment, Health & Safety regulation.

It can be seen in the Table 1 above that the phase out of Cr6+ based platings had to be implemented by the manufacturers by the 1st July 2007 for most vehicle applications, with a later deadline of 1st July 2008 for bolt and nut assemblies for chassis applications that was introduced in

the September 2005 revision of the ELV Annex II. Today, Cr6+ is only allowed in spare parts for vehicles placed on the market prior to the ban.

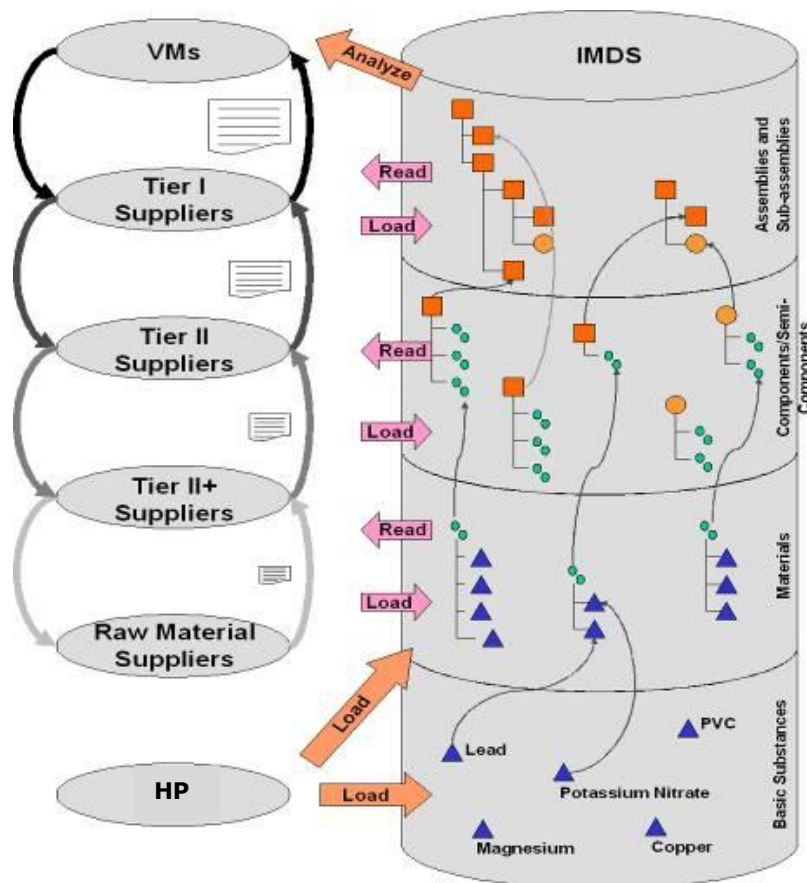
How the Phase Out was implemented

Whilst the obligation to comply with the ELV Directive falls on the vehicle manufacturer, facilitating the phase out can only occur with the cooperation of many actors in their supply chain. An overview of how this complex process was realised is presented below with a description of the compliance reporting tool used, and the perspectives from key parties involved in the process:

a. The Compliance Reporting Tool: The International Material Data System (IMDS)

A key element of the automotive industries response to the ELV Directive, and other regulation placing restrictions on substance content of vehicles is the International Material Data System (IMDS). IMDS is a centralised reporting tool that allows each tier of the supply chain to declare the material content of parts and materials to their customer(s). The majority of vehicle manufactures use IMDS, although some use alternative reporting and compliance mechanisms, notably Peugeot and Citroen who have developed their own system, MACSI. The process flow of IMDS is illustrated in Figure 1 below:

Figure 1: IMDS Declaration Process Flow



The reporting process is initiated by the vehicle manufacturer at the top of the supply chain by requesting that their Tier 1 suppliers report supplied assemblies into IMDS. In order for the Tier 1s to comply with this request, they must request parts data for any supplied components or sub assemblies from their own suppliers. In this way, the request cascades down the supply chain until the material manufacturers are reached. The material manufacturers report the material they

supply into IMDS to allow the lower tiers to report their components and assemblies to their customers.

At the end of the reporting process (i.e. once the Tier 1 has compiled all received data into data sheets for the assembly part numbers they supply, and submitted this data to their OEM customers), the vehicle manufacturers analyse the data to ensure compliance with the ELV Directive obligations, and other regulatory requirements relating to restricted substances in the markets they supply to worldwide.

The process therefore allows each tier of the supply chain to report to their customer the compliance status of their parts and materials.

b. Vehicle Manufacturers

The broad approach of vehicle manufactures for the phase out of Cr6+ was to ensure that their supply chain was aware of the forthcoming changes, check that they had adequate plans in place to carry out the necessary changes, and then verify that the changes had occurred. This was broadly implemented as follows:

- Update of engineering standards to control coating selection internally, and throughout the supply chain. For example, to inform of approved replacement plating processes for Cr6+ based chromate processes, and to prohibit the use of Cr6+ based chromate processes in future product design.
- Raise awareness with Tier 1 suppliers through direct communications via letter and email, and awareness raising events
- Planning the changeover for existing vehicle platforms. Cars already in production containing Cr6+ based platings required a transition plan to switch from Cr6+ containing parts to Cr6+ free parts. These parts had to be identified, and then an appropriate action plan put in place with the suppliers to facilitate the transition.
- Ensuring new vehicle platforms were engineered to be compliant with the Cr6+ phase out through the specification of updated engineering standards on new parts, or on new versions of existing parts.
- Ensure that Tier 1s has substitution plans in place through direct contact between OEM engineers and Tier 1 contacts responsible for the transition.
- Monitor the status of received declarations in IMDS to ensure that the changeover had been completed.

c. Tier 1 Suppliers

Tier 1s key role was to cascade their customers' requirements down their supply chain to ensure that they could support their customer requirements, verify the response from their supply chain, and then report the compliance status of their parts to their customers to confirm the switch to Cr6+ free coatings had been completed. This was implemented as follows:

- Cascade of customer requirements for parts via direct email, letter and direct contact through engineering and purchasing functions to communicate:
 - Deadlines for crossover of Cr6+ containing parts to Cr6+ free alternatives
 - Ensure that parts destined for new Cr6+ free vehicles were Cr6+ free

- Audit of plating facilities where necessary to check process requirements (there was some risk of cross contamination where plater were running Cr6+ and Cr6+ free plating processes in the same facility)
- Checking of received compliance data in IMDS to verify changes had been carried out where required
- Confirmation to customers that changes had been carried out via IMDS parts submissions and direct contact

d. Platers

The key actions of platers in implementing the Cr6+ phase out in automotive were research and development of alternative platings that could meet the performance criteria required by their customers. This was achieved as follows:

- Review of new OEM plating standards to R&D alternatives that met the performance criteria set out for Cr6 + free alternatives
- Managing the continued demand for Cr6+ based plating processes (which were not banned by most other industries). In many cases this required investment in separate facilities for Cr6+ containing and Cr6+ free facilities to avoid any cross contamination issues.

Key Lesson Learned

From the above it can be seen that the phase out of Cr6+ was a complex process involving the interaction of many organisations in the automotive supply chain. Following interviews with a number of parties involved in the process, and drawing on the authors own experience, a number of lessons learned can be derived and are summarised as follows:

a. Planning and Awareness

As a general rule, it was seen that companies who took a proactive and forward looking stance to compliance with the Cr6+ phase out were well prepared for implementing change under the ELV Directive. Such companies were quick to scope their exposure, had plans in place to manage their internal response and their supply chains response, and communicated well with their customers to report on their progress implementing the phase out.

Areas of weakness tended to be in lower tiers of the supply chain who typically had less awareness of the Cr6+ phase out, and less resource available to manage the issues presented by the phase out. In some cases the reporting process was perceived negatively as an additional cost burden out of scope of normal business activity. This perception was often compounded in companies that had only a small percentage of their customer base in the automotive sector (as other industries did not have similar reporting requirements), and were not requesting the phase out hexavalent chromium based platings. Similar problems were experienced by suppliers based outside of the EU where local market legislation did not ban Cr6+ in coatings.

Key lessons learned in terms of planning and awareness can be summarised as follows:

- Planning for change is an essential. Companies need to be well informed, have adequate systems in place in order to understand their exposure, plan suitable compliance strategies

with their supply base, and have reporting mechanisms in place to keep their customers informed of progress and demonstrate compliance.

- Communication throughout supply chains is critical. The whole supply chain needs to work in concert to be effective. Companies therefore need to ensure their entire supply chain is aware of their requirements.
- In any supply chain, there are weak points. These weak points need to be understood and appropriate mitigation measures applied. For example, to provide companies with limited resource, or with low awareness with the information, tools, training and support necessary to raise their awareness, and help them understand and meet their compliance objectives and reporting obligations.

b. Commercial Impact

A number of commercial impacts were also seen in the phase out of Cr6+. Trivalent chromate processes were initially more expensive than Cr6+. This meant that companies who strove for an early transition from Cr6+ to Cr3+ platings had an increase in cost to be negotiated with their customers. This price differentiation has now been removed or even reversed as the plating industry has now built up infrastructure and capacity to support the now widespread demand for Cr6+ free plating processes.

From a design and manufacturing perspective, there were also a number of cost implications. For cross over parts (parts originally specified with Cr6+ based coating that had to be revised to a Cr6+ free plating) some required requalification following the change (e.g. due to differing torque characteristics of Cr3+ based plating surfaces vs Cr6+), and all required a drawing change to document the change in plating specification. In the latter case, efficiencies were achieved by grouping drawing changes to encompass plating changes together with other necessary engineering changes to minimise the number of drawing changes required. As above, these costs had to be accommodated through negotiation between customer and supplier.

In some instances it was found that in certain applications plating alternatives did not always perform as well as the Cr6+ plating it replaced. As a result, some platers gained business and others lost business as their patented replacement performed better or worse than their competitors in the market.

Key lessons to be learned in terms of managing commercial impacts can be summarised as follows:

- As far as practicable, substitution of materials, substances and processes should be tailored to the production lifecycle of the product in question. Making a substitution mid production is far more costly than designing the product using only materials at low risk of substitution during the products production lifecycle.
- If a substitution mid production is unavoidable, there will be cost implications that need be to be negotiated between customer and supplier.
- The timing at which the substitution is made has a cost impact which needs to be factored into decision making. Make the substitution too early, and there will likely be higher cost

involved. Make the substitution too late however, and there are risks of non compliance or issues of redundant stock.

- When planning a substitution, the commercial impact needs to be assessed. The performance of your product may change – there may be an opportunity to gain market share potentially, but also the possibility of losing market share.
- Choosing a suitable substitute is also a key commercial decision. The alternative must meet certain engineering performance criteria, but also the nature of the alternative needs to be considered. Will the alternative itself require substitution in the future?

c. Reporting and Data Exchange

IMDS was shown to bring efficiencies to the reporting process. By providing a centralised data repository it capitalised on the fact that many automotive suppliers share customers and in some cases supply the same parts to multiple customers. Furthermore, as each tier of the supply chain plays a role in the IMDS reporting process, complete chain of custody could be traced between levels of the supply chain. This is now a legal requirement of the Type Approval process.

Many external communications were employed to facilitate the roll out of the Cr6+ ban. Issue of letters with deadlines and revised engineering plating standards were widely employed. It was often found though that deadlines for switching to Cr6+ free alternatives conflicted between OEM customers. In some cases this lead to the same part having different transition deadlines for different customers. In some situations, the Tier 1 supplier had little influence over their supplier to facilitate a particular deadline imposed by their customer. This was particularly the case for very large suppliers of standard components that were supplied to many customers (e.g. ECUs, brake components). In such cases, it was often the supplier who dictated when the part would become Cr6+ free and had little flexibility to meet individual customer deadlines.

The setting of deadlines in the legislation itself created some difficulties. As the legal requirement for compliance is from when the product is placed on the market, each OEM had to set a final deadline for supplied parts to become compliant well in advance of the legal deadline in order to avoid either non compliance, or stock redundancy issues. Such stock would either need to be scrapped, or the plating stripped and a compliant alternative applied in its place. This effectively created a concertina effect on the supply chain as each tier also implemented similar measures to avoid redundant stock.

Key lessons in the area of data exchange and communication can be summarised as follows:

- Industries need to take a common consensus approach as far as possible to enable their supply chain to take an efficient, coordinated approach to implementing phase outs
- Avoid duplication of effort within supply chain by developing industry standards for data exchange & reporting format (i.e. avoid the proliferation of reporting standards and tools)
- Lobby Government for workable solutions to implementing phase outs and bans such as 'point of sale' and 'within supply chain' deadlines to avoid stock redundancy issues

2. TRENDS IN PRODUCER RESPONSIBILITY REGULATION WORLDWIDE

The origins of Producer Responsibility legislation can be traced back in large part to the 1976 European Union Marketing and Use Directive 76/769. This placed blanket restrictions on the placing on the market of certain hazardous substances both on their own and in products (e.g. the ban of asbestos) where existing controls on exposure to humans and the environment were deemed inadequate to control the potential risks. In 1978, the US implemented similar controls in the form of Section 6 of the Toxic Substances Control Act (TSCA) which targeted CFCs. From the late 70's to mid 90's, a few more pieces of regulation emerged such as California Proposition 65 in response to consumer focus of hazardous substances used in products.

It wasn't until the European Union's Integrated Product Policy of the late 90's though that a step change was seen in the growth of legislative and industry driven initiatives to focus product lifecycle impacts. The End of Life Vehicles (ELV) Directive was one of the first Producer Responsibility Directives to emerge from the IPP framework, following the Packaging Waste Directive, and preceding the Restriction of Hazardous Substances Directive (RoHS) targeted at consumer electronics. Other territories around the globe have quickly followed suit. California, Korea, and China all have RoHS laws for example based on the EU version.

The European REACH Regulation is set to greatly accelerate the rate at which substances are risks assessed and targeted for removal from the market. As of today there are 46 substances on the Candidate List of Substances of Very High concern which contrasts starkly with the numbers of substance previously targeted for phase out or withdrawal within industry specific legislative instruments. Analogous pieces of regulation to REACH in other global territories already exist (e.g. Japans Chemical Control Law, Canadian Chemical Challenge), or are in the pipeline (reform of US TSCA).

This type of requirement, requiring manufacturers to manage substances in their production materials and processes and coordinate their supply chains response, is relatively new therefore. More importantly perhaps, it also raises a number of hitherto unseen business risks. From the analysis presented above, risks have already been highlighted looking at the ELV Directive such as low awareness in areas of the supply chain, or substitutes not performing as well as original materials resulting in gain or loss of market share. Looking at the current legislative environment, many more are emerging:

- Undocumented reformulation of materials. For example, where a supplier makes a substance substitution in a part or material, but does not inform their customer. This results in an unqualified part of material being used in production materials or processes. Notable examples of this include the substitution of lead containing to lead free solders in PCBs resulting in product failures.
- Substances disappearing from the market resulting in discontinuity of supply. Taking REACH as an example, a supplier of a substance produced in relatively small quantities may not wish to Register that substance for commercial reasons thus impacting on all downstream users of that substance. Similarly, a supplier may Register a substance under the REACH Regulation, but they are under no legal obligation to register the substance for all downstream uses, and indeed may not be aware of all its downstream uses resulting in similar discontinuity of supply issues. This particularly risk has been realised at the first

REACH Phase In deadline of December 2010, notably with Potassium Dichromate which was registered as an intermediate only.

- The sheer rate at which substances are being targeted for phase out or withdrawal also presents a risk in itself. Taking REACH as an example, the Candidate List of SVHCs is estimated to become more than 200 by the end of 2012, and by this time a proportion of these will have entered into authorisation procedures. This situation is compounded by existence of broader 'predictive' lists of substances that meet the criteria of being an SVHC (e.g. the Substitute It Now list). This places a significant burden on industry to explore alternative substances and processes and manage the related commercial and technical considerations referred to above in this report throughout their supply chain. This is a very different scenario from the ELV Directive which focuses on the phase out of four substances within a clear time table.

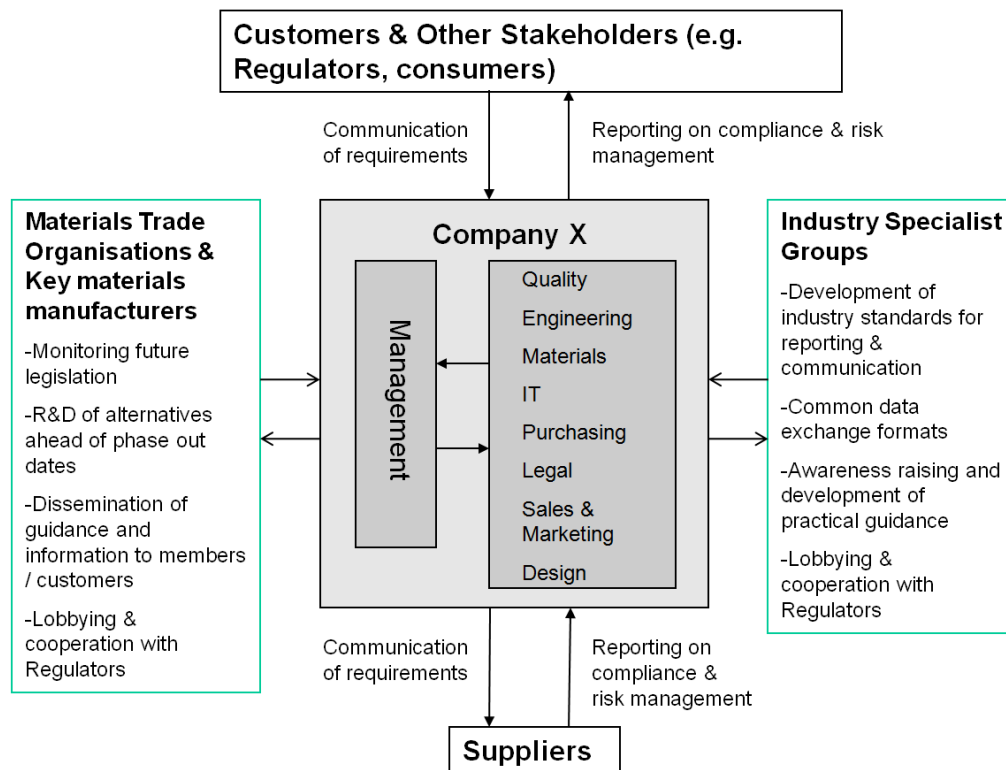
Not only does compliance need to be managed carefully for a given manufacturer in all the markets they supply to, but also the business risks need to be assessed and mitigated. As these are relatively new areas of compliance and risks management, it is arguable that companies and industry sectors as a whole consider what systems, processes and tools are necessary to respond to the challenges described above.

3. MANAGING PRODUCER RESPONSIBILITY WITHIN A BUSINESS MANAGEMENT SYSTEM

The sections above outline some of the key lessons learned from managing substance phase outs under the ELV Directive, and describes how the current legislative environment places even greater need on industry to proactively manage restricted substance related issues. The remaining sections of this paper propose a model for how individual organisations can effectively manage these issues through formal integration into their Business Management System (BMS), and what measures industry as a whole can take to prepare and support their supply chain.

Figure 1 below provides an overview of the key components of a business management system relevant to managing compliance and restricted substance issues. In addition, interactions with key parties outside of the organisation in their supply chain are shown. Section 3.1 below deals with the detailed actions being undertaken by each BMS component, and Section 3.2 describes the key interactions outside of the organisation (e.g. industry focus groups).

Figure 1: Components of an organisations Business Management System within context of other key stakeholders



3.1 Components of an Organisations Business Management System

Management

A BMS approach to compliance and risk management requires the coordinated effort of multiple departments to deliver the organisations overall strategy. A level above departmental level is necessary to ensure overall coordination and delivery in the following areas:

- **Assessment & Planning** – Scoping the organisations exposure to Restricted Substance related issues from a compliance and risk management perspective. For example, what are the legislative requirements on the products they manufacture in the markets they supply to, what are the compliance requirements, what are the business risks to the organisation and how can these be assessed and mitigated? From this process, a resource estimate can be determined, and an overall strategy developed.
- **Organisational Strategy** – The A&P exercise can be used to develop the organisations overall compliance and risk management strategy. For example, how should the organisation best deliver their compliance and risk management objectives – which departments should be involved, what is their role in the process, and how can performance be measured? Building a legal aspects register, setting key performance indicators and building audit protocols will be key components in delivering the overall strategy and measuring its success.

Design

Design departments have a critical role to play in the roll out of compliance and risk management strategy. For example, they need to understand what legislative restrictions apply to the components and materials and manufacturing processes they use currently, and how these may be impacted when considering material and process selection for the design of new products. Design decisions will be influenced by the overall company strategy on compliance and risk management, as well as other core engineering factors such product quality, performance and cost.

Purchasing

Purchasing has a role to play in managing compliance and risk from the organisations supply chain. For example:

- Assessing their suppliers systems for managing compliance and business risk (e.g. through formal questionnaire and audit).
- Ensuring suppliers meet their obligations to provide specified compliance and risk management data (ideally based on an industry standard).
- Encourage high quality data provision from suppliers through establishing business to business contractual agreements, incorporating performance into formal supplier ratings.
- Negotiating cost changes associated with substance or material substitutions.
- Benchmarking suppliers to assess the level of risk they present to the organisations compliance and business risk objectives and apply mitigating action accordingly.

Materials, Toxicology, EHS

Materials, Toxicology and EHS departments have key roles to play both in delivering compliance (e.g. ensuring compliance with safety data sheet compliance issues, and understanding the compliance status of current production materials), but also to support the organisations response to change. For example, to provide expert input into strategic decisions on alternative materials where a material have been identified as at risk of requiring substitution. E.g. what is the toxicological and legal status of the alternative - is there a risk it may itself be substituted in the foreseeable future? What are the technical performance issues of one alternative over another?

Engineering / Quality

Engineering and quality have a role to play in ensuring compliance of current production parts, and supporting any required material of process substitutions.

Compliance should be built into the manufacturing process by integration into the Production Parts Approval Process (or equivalent). Quality and Engineering also have key delivery roles in supporting material and process substitutions through activities such as qualification of new materials, parts or processes, or re-qualification of existing parts following a material or process substitution. In such instances, quality procedures should be employed to assess the performance of parts and processes following any change and the results fed back into the organisation for analysis and assessment.

Legal

Legal departments have a role to play in supporting the following areas of an organisations overall compliance strategy:

- Customer & supplier contracts – ensuring that suppliers agree to provide required compliance data and data supporting business risk assessment; reviewing corresponding customer requirements.
- Product liability – e.g. providing support on product liability issues legal issues relating to old stocks of parts (e.g. Article 33 compliance issues for spare parts).
- Due diligence defence – providing input on the organisations overall due diligence strategy. What documentation is required, how long should records be kept for, how should any identified potential non-compliances be handled?

IT

IT have a role to play in reviewing the company's existing IT infrastructure to identify where existing systems can be modified to support the organisations compliance and risk management strategy, identify where there are system gaps and mitigate accordingly through sourcing third party solutions, or building additional in house capability.

3.2 External Groups Interacting with the Organisations BMS

Industry groups

Industry groups have a vital role to play in the following key areas:

- Guide development of industry standards and tools for efficient, standardised data exchange in their supply chain.
- Share collective knowledge and experience to both build their overall industry approach, but also to feed into their supply chain to enhance and support individual organisations compliance and risk management strategy.
- Guide lobbying activity at the governmental level.
- Identify where data gaps exist to support legal compliance and risk management activity and mitigate accordingly.
- Benchmark their industries response to identify areas of weakness to support continual improvement.

Materials Trade Organisations and Material Industry groups

This group has a key role to play in research and development of alternative substances, materials and processes to facilitate forthcoming substitutions, as well as feeding into lobbying activity and technical groups such as the EU Technical Adaptation committee tasked with facilitating substance phase outs.

4. SUMMARY & CONCLUSIONS

This paper proposes that in order for industry to effectively respond to the rapidly evolving compliance framework surrounding restricted substances, and the incumbent business risks, individual organisations within their supply chain need to formally adapt their existing BMS. Specialist industry groups could support such infrastructures by providing expert intelligence and guidance to support the activities carried out by each component of an organisations BMS. For example, for a given identified business risk, develop guidance and supporting workflows to help an organisation to effectively respond to that risk.

This macro level of engagement is well developed across most industries through groups such as TF REACH in the automotive industry and similar groups in electronics, aerospace and other engineering industries. The challenge faced by industries as a whole is how to encourage individual organisations to actively manage these issues in order to ensure a coordinated response to compliance and risk management throughout their respective supply chains.

The array of instruments of change that could be employed to change the behaviour of whole supply chains are beyond the scope of this paper, however, suggestions for the frameworks within which these changes could be made are suggested as follows:

- Adapt existing established management systems such as ISO 14001, ISO 90001 or industry specific quality management systems such as TS 16949 to incorporate restricted substance compliance and risk management.
- Adapt existing industry guidance to encourage more formal integration of compliance and business risk workflows within a given organisations. E.g. Audit protocols could be added to the Automotive Industry Guide (AIG) on REACH, or the UK automotive REACH groups Code of Practice on REACH. Such guidance could be supported by targeted intelligence from the corresponding industry groups to inform their supply chain of new legislative and risk developments, and corresponding workflows to support any necessary mitigation.
- Develop new industry standards and initiatives with a broader remit than those mentioned above that are established primarily for REACH compliance. For example, there are a number of related issues on the horizon requiring similar workflows across whole supply chains (e.g. rare earth metals, conflict materials, and nano materials).