



## Environmental Compliance Update: Risks for Medical Device Producers

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In collaboration with [Joe Hage](#) and the LinkedIn Medical Devices Group

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**Joe Hage:** Hi this is Joe Hage. I have the privilege of leading your Medical Devices Group which as of this recording has 314,000 members worldwide and one of the reasons I believe we've grown so large is we have folks like Vanessa and Anne in the group who have great practical knowledge to share and they share it freely with you today. So Vanessa you're on the line.

**Vanessa Vasquez:** Let me introduce myself to everyone. My name is Vanessa Vasquez and I am the Sales and Business Development Director here at Compliance Map. I also have on the line my associate Anne Barr who is a regulatory consultant.

Just a brief talk about us and give you a little bit of our background on who we are, Compliance Map is a solution provider specializing in environmental regulatory compliance with the specific emphasis on material compliance such as RoHS and REACH, waste compliance such as EPR, supply chain management such as conflict minerals, origin determination and supply chain transparency.

Our solutions are aimed to automate all aspects of regulations. That will be covered today by Anne. This can include data collection, management of compliance information such as roll-ups and reporting in to authorities and customers.

In terms of us as a company, we have offices in the US and the UK and have other two decades of experience dealing with all areas of environmental compliance and product solution.

One of the most important factors of our business is we take a partnership oriented approach with our customers to make sure they are always on top of their obligations.

This is very important because a lot of the regulations that Anne will talk about today change rapidly. So a fast and innovative approach is needed to stay on top of the ever-changing landscape of compliance and your business obligations.

So that's a little bit of who we are. Now I'm going to hand it over to Anne who is our resident regulatory knowledge expert and who has worked extensively in the field of product environmental compliance to walk you through the topics and I look forward to the questions at the end of the session.

**Anne Barr:** Okay. Thank you very much Vanessa.

So as Vanessa said, the purpose of today's webinar is to provide you with an update on changes in the legislation that affect you as medical device producers.

So the first part of the webinar, we're going to focus on material compliance issues. So I'll be providing an update on RoHS, REACH and California Prop 65 legislation. And then the second part of the webinar, I'll be looking at product stewardship and your obligations under WEEE, battery and medical sharps legislation. And the format that I'm going to follow is I'll provide an update on each piece of legislation, look at how it impacts you as a medical device producer and then talk about how did that legislation is enforced really representing the case for compliance with these regulations.

So I'm going to move straight into the first topic which is EU RoHS and I'm sure you medical device producers who are selling into Europe everywhere that medical devices came into scope of EU RoHS from 22<sup>nd</sup> of July 2014. Apart from in vitro diagnostic medical devices that actually come into scope this year.

Active implantable medical devices are currently and for the foreseeable future out of scope. And that legislation restricts six substances or did until last year. And this directive was amended to include four additional substances and these substances are as follows. So these substances are used as plasticizers or in polymers and critically, they're already subject to authorization under the REACH legislation.

But from 22<sup>nd</sup> of July 2019 or for medical device producers of 2021, you'll have to comply with the requirement that your products can't contain homogenous material level any of these phthalates in a concentration of not .1% or not .01% in the case of Cadmium.

So very important update affecting medical device producers there. So we're now going to move on to China RoHS. So the EU was one of the first or was the first to bring medical devices into the scope of RoHS but China has recently announced a change in its administrative measures for the use of hazardous substances in Electrical and Electronic products and that will

come into force from 1<sup>st</sup> of July this year. And what this does critically is from China 1RoHS or RoHS1, if you like, that only covered electrical information products from the 1<sup>st</sup> of July 2016, the scope of China RoHS will be expanded to include all electrical and electronic equipment and that includes medical devices.

So what does that mean? What are your obligations?

Well like EU RoHS, there are also substance restrictions but in China RoHS, those substance restrictions will only apply to products that are listed in a compliance catalog and this catalog has not yet been published and there's no timescale being communicated at the moment. Those thresholds are the same as the original China substances for the moment.

Like EU RoHS, China RoHS will require some sort of conformity assessments. So basically you'd be required to prove that your products meet those substance thresholds. But only when they're listed in that catalog.

But what will apply from the 1<sup>st</sup> of July 2016 is the requirement for labeling. And so all electrical and electronic products that's sold in China has to be marked with either a green logo indicating that the product is an environmentally friendly product that can be reused and recycled or as in this case, an orange logo indicating what's called the environment protection use period. And what that is is that's the number of years during which hazardous substances will not leak out into the environment causing damage.

So the labeling requirement applies straight away. The final main obligation under this China RoHS2 is that the product's instruction manual has to contain the names of the substances that are present above the threshold. And this is represented in a table where you've got the part against the substance name. It's not with a cross if the threshold has exceeded or not in the event that it isn't.

So crucially, from 1<sup>st</sup> of July, medical devices come into the scope of China RoHS.

Now I'm just going to just talk a little bit about RoHS in other jurisdiction. So we've got EU RoHS and China RoHS bringing medical devices in scope. Norway has already done so. The obligations are the same as for EU RoHS. And except for these new phthalates.

So the work is actually ongoing at the moment to bring those phthalates into the scope of the Norwegian legislation and according to the Ministry of Environment there, that will be done so that the same date, so 2019 or 2021 for medical device producers will be the date by which those phthalates of substance restrictions will apply.

And a word on other RoHS jurisdictions medical devices are currently out of scope but I expect definitely in the countries with EU aspirations that they are likely to follow suit shortly.

So that's an overall discussion of the changes. Just want to recap on how this impacts you as medical device producers. How global RoHS affects you. And I've identified four principal ways here that apply to RoHS legislation worldwide.

So firstly and crucially, you have to meet the substance restriction thresholds either now or in the future when these phthalate restrictions apply in the EU.

Now EU legislation does actually allow some exemptions to the legislation if your product, the substance within it, replacement doesn't exist. So it can't be substituted if that substitute is actually unreliable or if the substitute actually has a worth impact on human health and the environment down the RoHS substance.

However, it's really important to note that these exemptions will only apply for finite time and in the case of medical devices, the maximum validity period for an exemption is 7 years. And it could be less. So for example, there's an exemption for lead in solders on circuit boards that are used in mobile medical devices that's due to expire on the 30<sup>th</sup> of June this year.

So it's really important to be able to manage the substances in your products so that you know what's in them and you can prepare yourself for substitution when the need arises.

So the second obligation in terms of global RoHS legislation is in terms of conformity assessment. So first the EU and China require you to prove that your product meets the substance restriction and in the EU, that requirement involves producing what's called a technical file and what this does is it identifies the product, identifies how it's designed and built and how it conforms with the requirement and that will include a risk assessment. And at the end of that process in the EU, you also will have to produce what's called a declaration of conformity declaring that not only is the product in conformance with EU RoHS but it's also in conformity with all the legislation that allows that product to be placed on the EU market.

And that is indicated by the CE Mark which is the third requirement under RoHS legislation. So in the EU, it must be labeled with the CE Mark shown on the icon and in China, it's the Environment Protection Use Period. The orange or green logo.

And the fourth major requirement of the RoHS legislation is that you would have to provide information. So in the EU, you have to identify the product for example by serial number and also provide contact details of the manufacturer and in China, you have to include the Hazmat table. That list of substances in the parts in your production manual.

So four main requirements and you can say this has major impact on medical device producers such as yourselves in terms of resources both in product development and in meeting the existing requirements.

So I've talked a little bit about how you comply. What happens if you don't?

So I'm just going to present a few case studies of enforcement in the EU. So because RoHS is a CE Mark directive, you have to or the member states have to carry out inspections to ensure that companies are complying with RoHS and if they're not, they're required to take appropriate action.

And the legislation stipulates that if there's a serious risk, that product has to be withdrawn from the market until that risk is removed. So enforcement in Europe varies considerably between the different states but in general, they'll use a risk-based approach. Because it is a European directive, there will be some joint projects for high-risk products but also the legislation allows consumers or critically, competitors to make complaints for reactive enforcement activity.

So here are a few examples below. So in Finland for example last year, there were five inspections of medical devices but interestingly, there was an 80% non-compliance rate. The response was to issue advice as to how these devices could come back into compliance.

In the United Kingdom, a couple of years ago, there was a specific project on medical devices, again a high non-compliance rate 50% and there was a 30% non-compliance rate in respect of the substance restrictions not being met or not being met with an exemption in place.

Again, the response was to issue advice. So the authority really do want to participate with companies in order to ensure compliance.

Just to give you an idea of the overall level of enforcement, not just specific to medical devices is an example from Norway here under the Norway Product Regulations and that shows that they carried out 300 inspections for their product regulation and they actually found a 70% non-compliance rate. Again, they dealt with it by the provision of advice.

But it's important to note that prosecutions will occur, product withdrawal will occur if there's a serious risk posed and here's an example from Norway from 2013 where a company had to pay around \$100,000 in respect of non-compliance with the RoHS aspect of their product regulations.

So quite a potentially hefty fine but also you've got the issue of publicity that's associated with it that can obviously have an impact on your brand, your customers, your shareholders. So very important to comply from that aspect.

But also, you should really think about your customers as well and their requirements for companies to have strong material compliance processes in place. Governments, large

companies often require you to have these internal control procedures and if you can demonstrate conformity, you're a lot more likely to be able to win these contracts.

So strong business case for compliance with RoHS as well.

So the material compliance part 1, that's finished. We're going to move on now to REACH. So the two main updates to talk about regarding REACH.

So the latest batch of substances of very high concern were added in December and there are now 168 substances of very high concern that require notification and communication under the REACH regulation.

There's currently 4 substances that are proposed and so we can expect that number to increase come June. But one very significant change that's happened over the last year is a ruling by the European Court of Justice regarding how the not 0.1% threshold for notifying and communicating SVHC's in article should be applied.

And critically, that ruling states that you have to apply that threshold to each article that's incorporated as a component of a product rather than the entire product itself.

So that has significant implications but what exactly are your obligations under regulation as a medical device producer?

Well, there's three main obligations. The first one is in respect to the registration of substances that are intended to be released from articles.

So if you're producing one of these or more and the total amount of substance present in all the articles that have that intended release exceeds 1 ton per year, then you must submit a registration dossier to the European Chemicals Agency unless that substance is already being registered for that use.

The second main obligation is relating to notification of substances that are included via a Candidate SVHC list. So if your article and this is any component article as well, contains an SVHC with a concentration of not 0.01% and the total amount of the substance in all the articles produced or imported which exceed this threshold, exceeds 1 ton per year, then you're going to have to notify.

Just to note that the duty to notify actually only applies if you have made or assembled the article yourself. It would be the upstream producer that would be responsible for the notification.

Again, if the substance is already being registered, you will not have to submit a notification and if you could prove that no exposure of the substance could occur, then you wouldn't need to notify either.

The third impact of REACH legislation on medical device producers is in terms of communication. So if your articles or the component articles contain an HVHC that have a concentration of not .1%, then you to provide relevant safety information to professional recipients. And a minimum, that would have to be the name of the substance. You also have to provide this information to consumers if they request it within 45 days of that request.

So a huge information requirement here in terms of communication of substances of very high concern. So what this suggests is that you really need to have a system in place to communicate substances and be prepared for changes that might occur or do occur in the candidate list.

So many of our clients actually use a form material disclosure so that they're anticipating addition of new substances of high concern so that they can communicate that out easily.

So you can say that there is quite a big impact of this ruling on medical device producers. So you really need a system in place that you can monitor and report on those substances.

So given those quite challenging requirement, how is REACH enforced? Well, REACH enforcement is so coordinated between the member states and those joint projects undertaken. But like RoHS, there's also reactive enforcement activity.

Now to date, there hasn't been any joint projects on registration notification and communication of substances in articles. They're prioritizing based on risk so focusing on substances themselves but there has been enforcement activity at member state level.

And again, this is probably in response to consumer or competitor concerns.

So I've got some examples here that were taken from the latest enforcement report. Member states have to submit one of those to the Commission every 5 years and so these are statistics from 2014.

And what you can see here is only 8 of the member states have actually reported any enforcement activity in respect to registration and notification of substances in articles. And of that activity, only 7 cases of non-compliance were noted in Germany and 2 in Poland.

In terms of communication of substances in articles, you can say that 9 countries reported enforcement activity. In this case, non-compliance rates were higher. So 26 cases of non-compliance in Germany, 79 in Poland, 15 in Sweden.

Critically, of all these countries, only Germany, Poland, UK and Austria have secured any convictions for any REACH violation in that year.

And the UK one I know was not to do with substances in articles. Again, the most effective, the cheapest way for the enforcement authorities to enforce REACH is to provide advice. Most companies want to comply and they just need the information in order to be able to do so.

But you can see that enforcement activity does occur and the potential enforcements, the potential is strong in terms of member states can impose fines or in some cases imprisonment. And with that competitor activity driving enforcement activity, it's very important to protect yourselves against that.

So I've looked a little bit about RoHS and REACH. We're now going to move on to the final material compliance update which is over the water and we're going to talk about California Prop 65 which is also a material compliance issue for those of you doing business in California.

So Prop 65 requires California to produce a list of chemicals every year that are known to cause cancer or other reproductive harm. Last year, we had 11 substances added and it's being worn so far in 2016.

But critically, a change that has recently come in and takes effect this month is that if you are providing a Prop 65 warning, you have to provide information for inclusion on a website if the Office of Environmental Health Hazard Assessment request it. And you have to do that within 90 days of that request.

The information that you're required to submit would be the name of the chemical, where you might find it in the product or the premises, what the concentration of that chemical is, how people might be exposed to the chemical and at what level.

So how does this affect you as medical device producers?

Well, Prop 65 requires you to provide a clear and reasonable warning before you expose anyone to a listed chemical. So the impact of these changes is that within a year of the substance being listed, you must be able to provide that warning. And after the substances' being listed and you providing that warning, then you must be able to respond to the Office of Environmental Hazard Assessment if they request information.

The challenge is perhaps there are over 900 substances listed on the California Prop 65 list. So you have obligation to monitor and report on those substances. So you clearly need to have a good system in place for this.

And the enforcement statistics are a really strong driver to comply with California Prop 65. Prop 65 is very different in terms of enforcement to RoHS and REACH in that lawsuits can actually be filed by anyone who's acting in the public interest. It isn't just dependent on the activity of the enforcement agency.

And because of this, enforcement in California is very very active and the latest report from 2014 shows that there was 663 settlements for Prop 65 violations and now totaled over \$29,000,000. It's a really significant amount here.

Unfortunately, the medical device industry was not exempt from this and two well-known medical device companies faced fines here. So they have to pay settlements of \$60,000 and \$89,500 respectively.

So again, this says that if you want to avoid these large fines and the adverse publicity that goes with it, you really need to be able to monitor these chemicals and communicate exposure. Just to point out also that a lot of the Prop 65 chemicals are also RoHS substances and or HVHC's.

So if you have a system in place that can manage all of your material compliance responsibilities, then that's going to be a lot more efficient and therefore cost-effective.

So that's our material compliance update for RoHS, REACH and Prop 65 completed. I hope that's given you some good information on the changes and why you should comply with them.

And we're now going to move on to the second part of the webinar which is about product stewardship. And I'm going to talk about changes that have happened over the last year with respect to WEE, battery and medical sharps legislation.

Again, I'm going to follow the same format. So I'll update you on the legislation, then talk about how that legislation impacts you as a medical device producer and then talk about how the enforcement of the regulations are taking place and why you should comply from a compliance perspective and from a business perspective.

So a major change that's happened in Peru that will take effect from August 2016 is that in Peru, all categories of WEE, the 10 traditional EU WEE categories have come into scope of Peru's WEE legislation.

So what this means is that if you're a medical device company producing products in Peru, then you're going to be required to submit WEE management plans by August 2016 and they would be approved by the Ministry and once approved, you'd have 6 months in which to implement it and then you're required to report on that implementation every year.

So a major change there in Peru.

I thought it might be useful to just recap on how WEE and battery legislation impacts you as medical device producers not only in Peru but worldwide.

So generally, WEE and battery legislation encourages or requires that products are designed to facilitate reuse and recycling at the end of their lives. They also would require you to register as a producer of electrical and electronic equipment or batteries and you would be responsible as with all product stewardship regulations for financing the recovery and recycling of those products at the end of their lives.

You also generally need to label the products. So in the EU, you can say from the picture there that WEE and batteries have to be labeled with a crossed-out wheel bin symbol indicating that you can't dispose of it in the normal rubbish.

You also in the case of batteries have to label if chemical content thresholds were exceeded and you also have to label with the capacity of the battery.

You're also required to provide information to consumers about how to dispose of the products at the end of their life and in EU, you're also required to take those, the WEE product back at the end of their lives.

There are also obviously WEE, the substance restrictions for WEE are contained in the RoHS legislation but in terms of batteries, there are substance thresholds as well. The first one does apply to medical device producers in that the batteries can't contain more than 0.0005% mercury. The other requirement for cadmium doesn't yet apply to medical device producers.

Quite a lot of obligations there. How companies generally comply with these requirements? They would join a compliance scheme in respect of the financing, the recovery and the recycling of the products and ensuring product take back.

And compliance schemes are often the most cost-effective way to manage your obligations and it can also help you if you ever have an enforcement inspection. But what is the level of the enforcement activity in Europe?

Well, I've got some examples here. So you can see that in Ireland in the second half of last year, there are actually 242 inspections that took place and they actually found 80% non-compliance rate. So very very high again.

And the response was to issue instructions of how those products could be brought into compliance.

Following that activity, the level of compliance was reduced, non-compliance was reduced to 41% but now before the action was taken, this puts us a result, most of this was relating to

distant sellers. So it's very difficult for the enforcement authorities to enforce. But in certain cases when it's deemed in the public interest, fines will occur, prosecutions will be undertaken and here is an example from Ireland where a CCTV company was fined €22,500 and that was for non-compliance with WEE.

Just to point out again, like REACH that the level of enforcement activity varies considerably between member states. So Poland as we saw earlier was very active with REACH. They've also been very active with battery legislation and so you can see that in 2015, they carried out 760 inspections of batteries at almost 200 different businesses whereas in the Netherlands, they only undertook reactive inspections.

And just to illustrate the level of non-compliance in Norway, they found that 25% of batteries that they inspected had not been marked with the crossed-out wheel bin symbol and there was also non-compliance issues in respect of labeling of chemicals and labeling of the capacity of the battery.

Again, the companies were required to undertake corrective action rather than being prosecuted.

So this represents the level of enforcement activity in Europe but the case for compliance isn't just about enforcement especially regarding WEE and batteries because the legislation is about designing your products so that they can be recycled and facilitating that recycling process.

So if you're designing your products so that you're reducing the amount of materials that you're using, obviously that has a potential to reduce your cost not only in terms of the material cost but also in terms of the compliance cost as the compliance schemes often use weight-based phase.

Additionally, if you're taking back products and you're designing them so they can be recycled, you can either reuse those components yourself reducing your cost or you can sell those on to secondary recycling markets.

So it can often be a really good business decision to comply and exceed the requirement of the WEE and battery legislation.

So that's WEE and battery. It's the first part of our product stewardship update. And I want to move into the final update which is in respect of medical sharps. And this will affect you if you're producing medical sharps. So that's syringes, needles that are destined for consumers in Canada.

So if you are producing medical sharps in Prince Edward Island province of Canada, you are now in scope of the Materials Stewardship Recycling Regulations.

If you're selling or producing in Ontario, you're already liable for product stewardship in respect to medical sharps but critically, other provinces are following the leads of Ontario and Prince Edward Island and they are likely to implement producer responsibility for medical sharps as well.

So how does the medical sharps legislation impacts on you as medical device producers?

Well, if you are selling indirectly or directly medical sharps to consumers in Ontario and Prince Edward Island, then you're required to operate or participate in an approved stewardship program.

The WEE and batteries, you can join a collection scheme. So what I'm familiar with is the Health Products Stewardship Association Compliance Scheme and that scheme and any approved stewardship program is designed to provide consumers with an easy way that they can dispose of the used sharps and also ensure that those used sharps are safely transported and disposed of. Consumers are educated as to the best ways to dispose of those sharps and the compliance scheme also has to report annually on the quantity of sharps that they collect.

So there's obviously a financial implication to medical device producers under this legislation that you need to plan for. But there is a strong argument for compliance. Obviously it's new legislation so no prosecutions yet. But the potential level of enforcement activity is high or the sanctions imposed are high.

So in Prince Edward Island, the Environment Protection Act provides for fines up to CAD 50,000 and 90 days imprisonment and in Ontario, those fines are even higher. But again, like Europe, recognizing that's new legislation, the enforcement authorities are really focusing on education at the moment.

Okay. So that's the material compliance and the product stewardship sections covered. I've now covered an awful lot of information. But just to summarize, what I think you should be able to take away with you today is an understanding that environmental legislation is changing all the time. There's a real requirement to keep track of this. And that affects you as medical device producers. You have responsibilities to play in terms of material compliance as well as product stewardship and that obligation is going to continue in the future.

I hope I've also shown based on the enforcement statistics that there's a really high rate of non-compliance and that potentially is affecting your ability to win customer contracts and you're putting yourself at risk for increased enforcement activity in the future if that's observed.

I've also shown that the enforcement regimes vary from a participants reproach generally in Europe and Canada to a much more litigious approach in California.

But when you're basing the requirements of the legislation, you don't just need to avoid the California fines but there also might be other drivers for compliance. So the ability to win customer contracts for having really strong practices in place. The idea to promote product innovation and to access these secondary markets for recycling.

So I just want to thank you for listening to me for the last 45 minutes. You will find on our website, there's a lot more information about the different legislation listed in the resources section but for the moment, I'll be really happy to answer any questions that any of you have and I'll just hand you back to Joe so that he can fire away.

**Joe Hage:** Anne, you did such a nice job. I'm really glad I invited you and on a personal note I like your accent. So I enjoyed listening.

**Anne Barr:** Thank you.

**Joe Hage:** You have a number of questions on queue. The first is from Khalid who asks, what is the transition period for RoHS for IVD manufacturers?

**Anne Barr:** IED manufacturers ...

**Joe Hage:** IVD.

**Anne Barr:** I'm sorry. IVD. Oh in vitro medical devices?

**Joe Hage:** He believes it starts in July. By which date do you need to comply?

**Anne Barr:** Yes. That's the 22<sup>nd</sup> of July. You need to comply. So you need to have produce your own technical files by then. You have to have met the substance restrictions by then and I would advise looking at the list of exemptions to see if they might apply already.

**Joe Hage:** Where would you see those exemptions? Do you have a link maybe you could share? Or Vanessa in the background if you want to shoot it to the audience? By the way, the audience will see that I sent a link to the slides. I've already uploaded them. So you can get them right away.

**Anne Barr:** Joe? Sorry. Joe? Can I just say yes? So the European Commission website produces a consolidated version of the RoHS legislation. So that includes the changes in respective phthalates that I mentioned but it also contains a consolidated list of the exemptions and what I would suggest is that people go to the Commission website, look at the consolidated version first and then look at the ... below that is usually secondary legislation. So they'll have a date and anything after that, they'll be able to access and find out what exemptions are valid now.

**Joe Hage:** Okay. Thank you for that. Rika asks, to which extent are medical devices in scope of the EU packaging directive?

**Anne Barr:** They are in scope. So the packaging directive would require you medical device producers to meet the recycling and recovery obligations. They do vary slightly between member states in terms of implementation but in general, you would have to join a compliance scheme. You would have to meet the essential requirements of the packaging legislation.

So that means there's a threshold for heavy metals and there are also design requirements so you're minimizing these packaging but any producer of packaged products would be liable into that if they meet the national thresholds.

**Joe Hage:** Thank you. Shout out to Adam Wheeler in the house who just gave the group the link that we talked about. So thank you Adam.

Rika also asks, do you have any data on enforcement in China on Chinese RoHS?

**Anne Barr:** That's really interesting question. So the Asian authorities generally won't share that information at all. They say it's confidential. They won't show that.

**Joe Hage:** That strikes me as odd.

**Anne Barr:** Yes. Yes. I specifically spoke to Taiwan recently to try and persuade them but unfortunately not.

**Joe Hage:** Okay. Gem asks, if our company is an OEM and not a chemical manufacturer, how likely is it that there are any HVHC's in parts we purchase? He clarifies, he's heard that as an OEM your number is often very low. How likely is it that notifications are required since 1 ton annually is needed?

**Anne Barr:** So that's the requirement for registration if your products are ... if the substances are in excess of 1 ton per year but critically and I think this is what a lot of companies think is that they're not affected by REACH because they're not a substance manufacturer.

The fact is, if they are a producer of an article, they have those three obligations under REACH that I talked about.

So if the article they're producing is releasing substances, then they have the registration obligation. The notification obligation only applies if you are meeting the ... if it's an HVHC over not .1% and that use of substances hasn't already been registered.

You would hope that the person supplying you with the substances already registered it for that use and it just highlights here the importance of supply chain communication so that you have an understanding of what chemicals are in your product.

But with the third obligation regarding the communication, that is something that you are obliged to communicate. As a professional user, your supplier should be providing you with that information and that's something you should ensure that you get.

**Joe Hage:** Okay. Next question comes from my friend Mitch so give him a good answer. Does Anne have any information on conflict minerals specifically any enforcement actions?

**Anne Barr:** So in terms of enforcement, I don't have any information. Again, that's quite a new piece of legislation but I can certainly find out for him and provide some information.

**Vanessa Vasquez:** Yeah Anne this is Vanessa and I'm going to step in. We do have information on that and we could actually send it offline. We just did not have it prepared for this presentation but we do have information on conflict minerals and enforcement and we can send you some details offline if you're interested.

**Joe Hage:** Vanessa, do you think you'll have that quickly? I might include it in my email out to the group.

**Vanessa Vasquez:** I need a little bit of time.

**Joe Hage:** Okay. We can do a separate one when the transcript is ready and I have a question here from Beth who asks, can you work with SAP? What other systems does Compliance Map integrate with?

**Vanessa Vasquez:** Yeah I'll answer that question too. We integrate with all ERP systems from Agile to Oracle. Sometimes we work with clients that have a manual Excel set up. So we are compatible with all SAP and any type of system we're probably working with.

**Joe Hage:** Okay. Well, we're almost at the top of the hour. I want to thank Anne and Vanessa from Compliance Map. You're all welcome to virtually applaud or type in your thanks and hurray's. I think you guys did a great job. It's a great value and I will share this information out with the broader audience as well.