

Conflict minerals: What does Dodd-Frank Section 1502 mean for companies in the Medical Device Industry?

May 2013

Agenda

- Conflict minerals background
- Scoping and conducting a Conflict Minerals program
- Key activities and critical success factors
- Legal challenge
- Questions and answers

Conflict Minerals Background

A perspective on the conflict in the DRC that is not commonly shared

Video: <http://www.youtube.com/watch?v=aF-sJgcoY20>

What is the impact of the Conflict Minerals rule?

Number of companies impacted:

~6,000

Issuers will need to perform some level of due diligence

>4,500

Issuers will need to submit an audited conflict minerals report

~278,000

Additional companies will also be impacted by customer requests

Compliance cost estimates:

\$3-4

Billion in total compliance cost

\$207-609

Million in annual ongoing compliance cost

\$1.2

Billion in compliance costs incurred by suppliers to comply with customer requests

Source: SEC Rule

SEC high level requirements for Conflict Minerals compliance

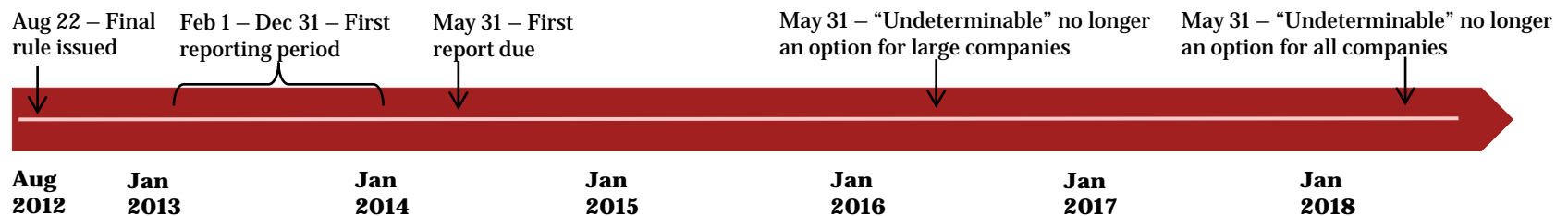
What are “conflict minerals”?

- Conflict minerals, as determined by the U.S. Secretary of State, may finance conflict in the Democratic Republic of the Congo (DRC) or adjoining countries
- The conflict minerals are:
 - Tantalum, Tin, Tungsten and Gold = 3TG

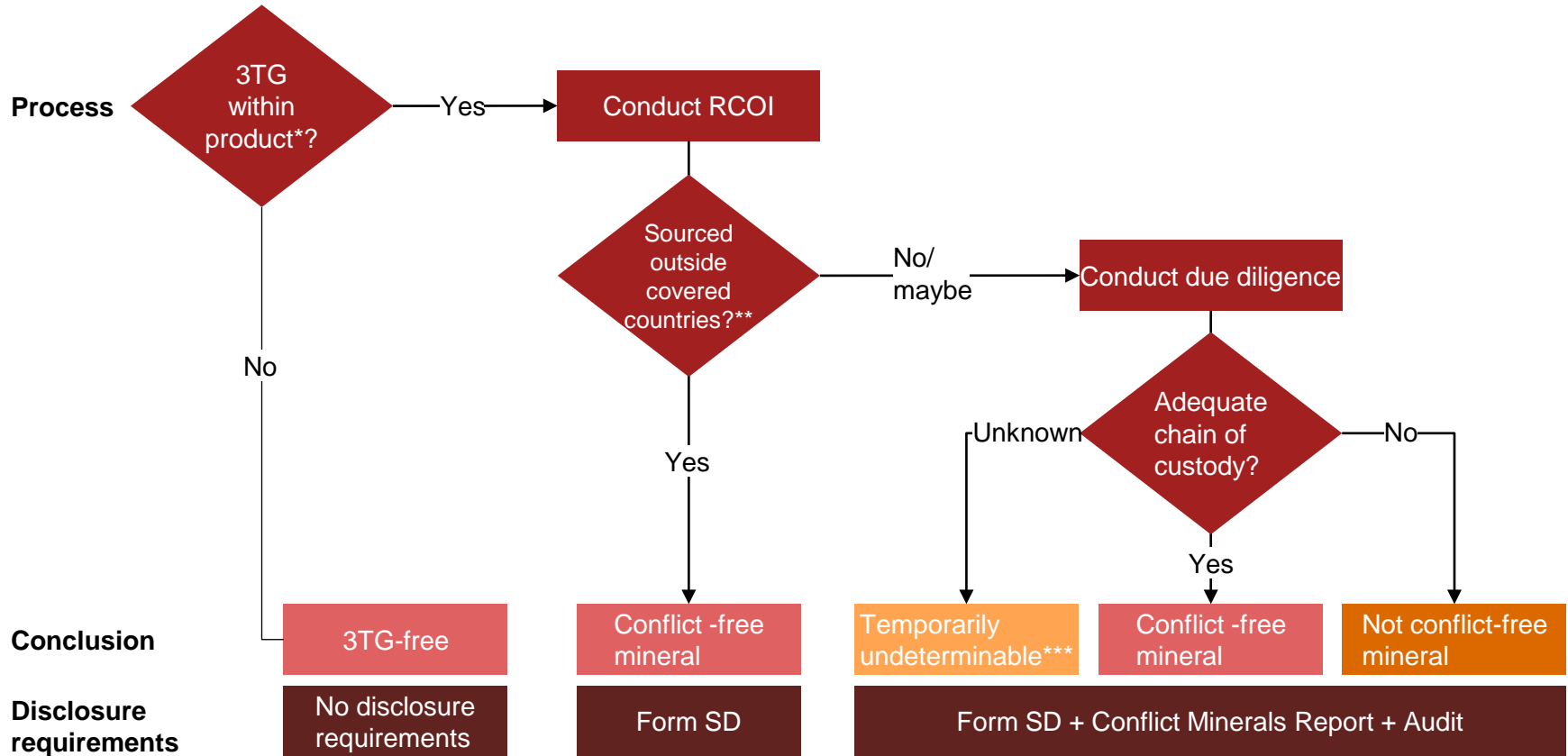
Who is in scope of Section 1502?

- Any company that files periodic reports under Sections 13(a) or 15(d) of the Exchange Act who:
 - Manufactures or contracts to manufacture products, **and**
 - Uses 3TG that are necessary to the functionality or production of those products

When does compliance begin?



The origin and conflict status of a product's 3TG will trigger different audit and reporting requirements



* Products the company manufactures or contracts to manufacture on its behalf

** Or comprised of recycled/scrap materials

*** The undeterminable option is only available for the first two years for larger companies, and four years for smaller companies. This option does not require the independent audit for those products.

In-scope companies are found to be in one of four stages of compliance execution

Implementation progress has been varied among industry groups

Waiting

- Not aware of Section 1502, or how it can apply to them
- May be aware but are waiting for the final rules

Small steps

- Generally aware of legislation
- Posted policy on website
- Have begun some level of identifying which products/which suppliers may be exposed
- Have not implemented OECD guidance

Active Preparers

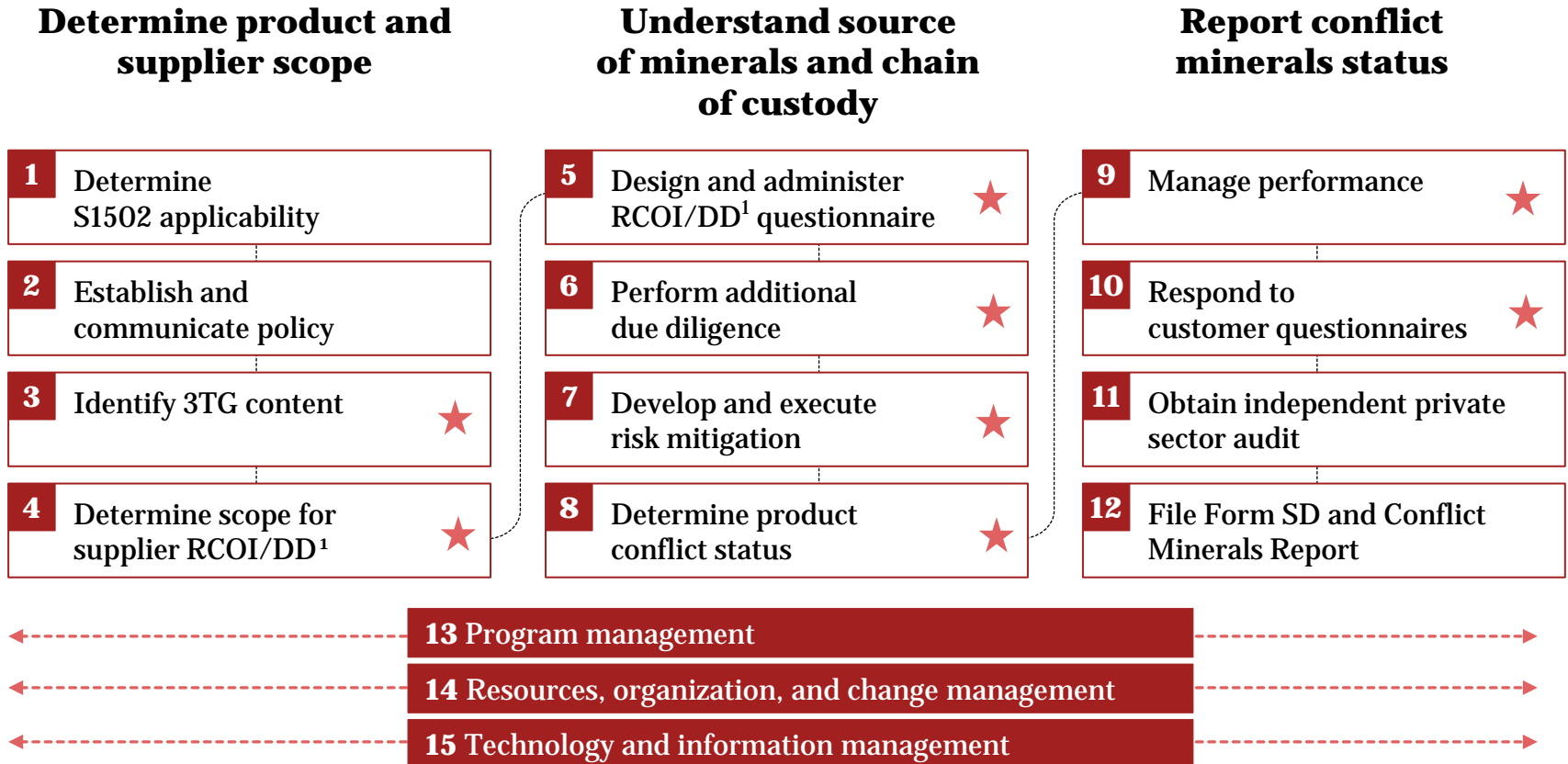
- Understand complexity of issue
- Highly aware of industry tools
- Have identified core products and suppliers to analyze
- Begun implementation of several steps in the OECD framework (policy, inquiry)
- May have begun to implement a software solution
- Tend to be struggling with how to prioritize and perform due diligence

Leaders

- High awareness, high knowledge
- Leading and initiating industry initiatives
- Implemented several steps in the OECD framework
- Set and disclosed public targets to be conflict free
- Audited smelters
- May already be conflict free in certain areas
- Already providing some level of reporting on their website
- Have been waiting for final rules before conducting making any significant system changes or conducting full due diligence

A Conflict Minerals program architecture should align with SEC and OECD requirements

Successful program implementation requires a standard and consistent approach



¹ Reasonable country of origin inquiry/due diligence

★ Denotes process steps that may be enabled by technology tools

¹ Reasonable Country of Origin Inquiry / Due Diligence

3TG's are prevalent within the medical device product portfolio

Product Type	Tin	Tantalum	Tungsten	Gold
Hearing Aids	X	X	X	X
Pacemakers	X	X	X	X
Suture clips		X		
Skull plates		X		
Surgical instruments	X	X		
Wire meshes		X		
Prosthetic devices & rods		X		
Medical instruments	X	X	X	X
Diagnostic equipment	X	X	X	X
Storage and retrieval systems	X	X	X	X

Product Packaging Considerations

Is packaging necessary to the product's generally expected function?

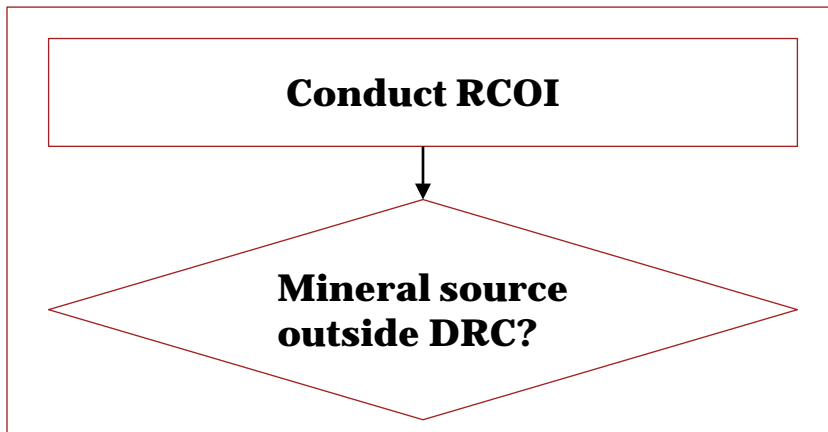
- Product Protection
- Sanitization
- Temperature control
- Sterility
- Durability

Key scoping considerations in launching a successful Conflict Minerals program

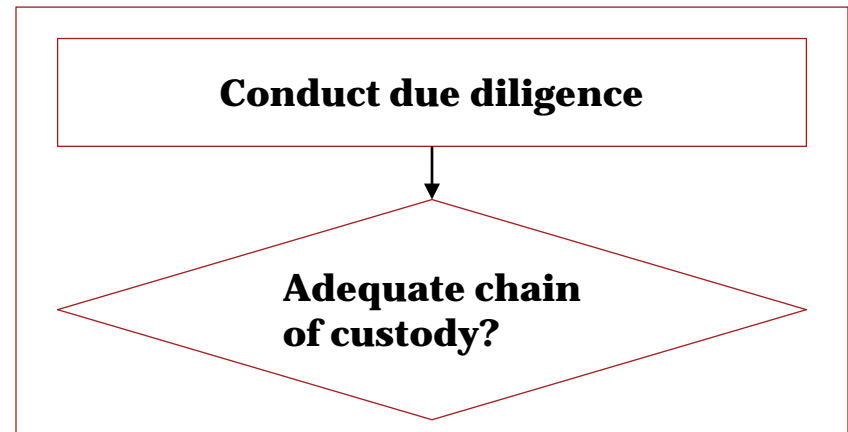
- Identify high level product 3TG
- Assess organizational readiness (complexity, process consistency etc.)
- Define key terms:
 - Necessary to functionality
 - Necessary to production
 - ‘Influence’ - contract manufacturing / private label and company exclusive products
 - Product
- Consider other products entering the ‘stream of commerce’
- Evaluate impact due to strategic business relationships / JV’s / licensing
- Identify scrap/recycled

Most companies will need to perform some level of supply chain assessment to meet both the RCOI and DD requirements

Where?



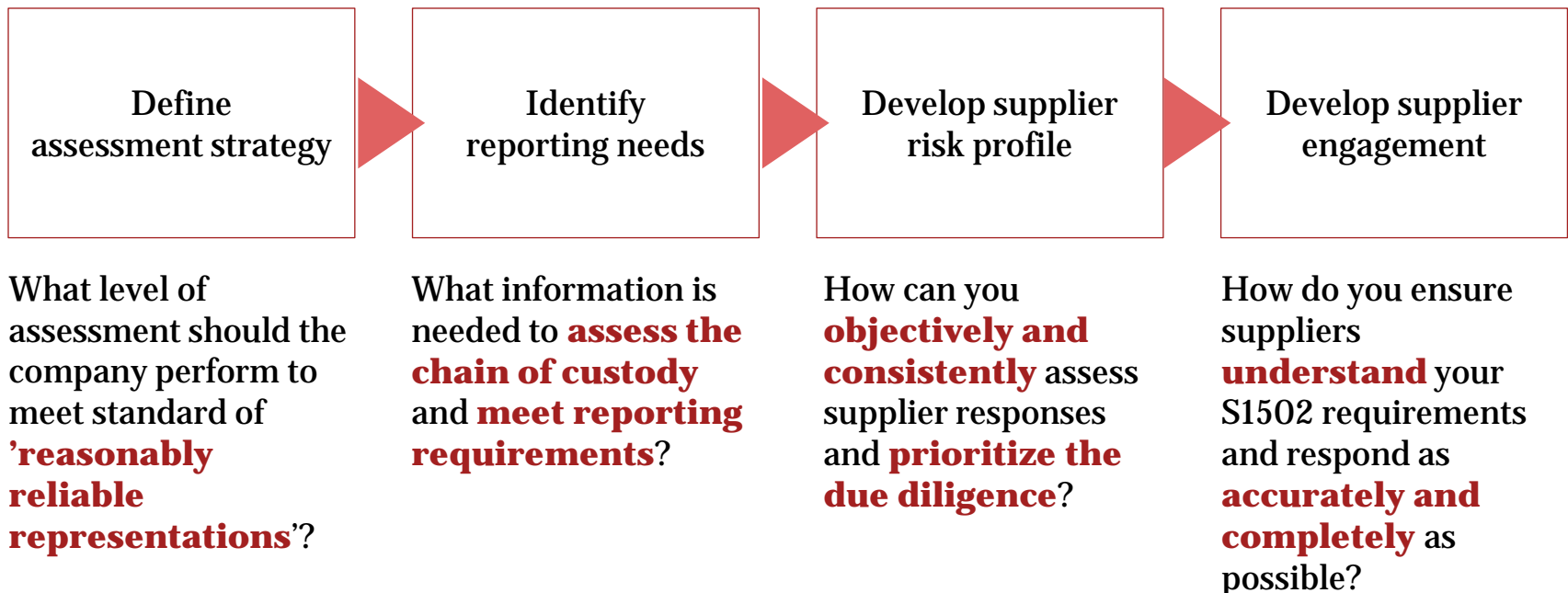
Who?



- Supply chain transparency is complex
- Supplier understanding is limited and immature
- Suppliers will often provide the quickest response vs the right response
- Only a limited number of companies will be able to do the RCOI only
- Supplier responses need to cover the products they supply you

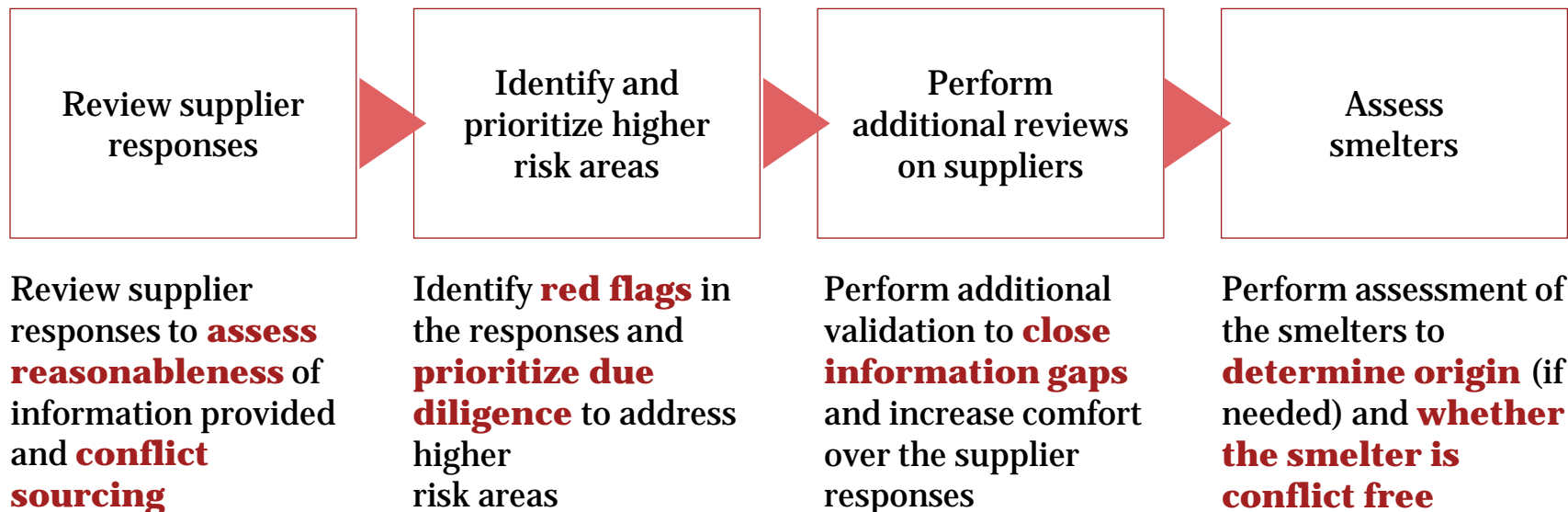
A clearly defined strategy will ensure that the assessment process is designed and executed effectively

As you design your program, you should start with your desired end-state in mind remembering that your design will eventually be subject to an audit



Execute a defined, risk-based evaluation process across all supplier responses

Until supply chain transparency matures and improves, companies will face increased risks of the supplier responses containing inaccurate or incomplete information



Due diligence guiding principles

Execute a defined, risk-based evaluation process across all supplier responses

While the SEC did not define what is reasonable, there are overall guiding principles from the Rule and other standard due diligence practices to keep in mind:

- Reasonable and in good faith
- 100% supplier response is not required, but red flags should not be ignored
- Supplier representation needs to be ‘reasonably reliable’
- Skilled individuals should evaluate the information

Exploring reporting requirements: Preparing the Form SD and Conflict Minerals Report

First filings are due May 31, 2014, for Jan 1 – Dec 31, 2013, and calendar years thereafter

Timeline for reporting and audit

<i>Calendar year</i>	<i>Origin of 3TG minerals</i>	<i>Form SD</i>	<i>Conflict Minerals Report</i>	<i>Independent audit required</i>
<i>2013 and 2014</i>	1. DRC and covered countries	Yes	Yes	Yes
	2. Outside the DRC and covered countries	Yes	No	No
	3. Unknown (undeterminable option available only in 2013/2014)	Yes	Yes	No
<i>After 2014</i>	1. DRC and covered countries	Yes	Yes	Yes
	2. Outside the DRC and covered countries	Yes	No	No

Independent Private Sector Audit (IPSA)

It is common that the independent audit requirements have been misunderstood

Independent Private Sector Audits include:

- **Audit required when issuer is sourcing from the DRC**
- **Audit report addresses issuer's due diligence from two aspects:**
 - **whether the issuer's framework conforms to a recognized framework**
 - **whether the description in the Conflict Minerals Report is consistent with process undertaken**
- **Form of audit report:**
 - **Attestation (must be performed by CPA); or**
 - **Performance audit (not required to be performed by CPA)**
- **Exemption for temporary 'Undeterminable' products during transition period**

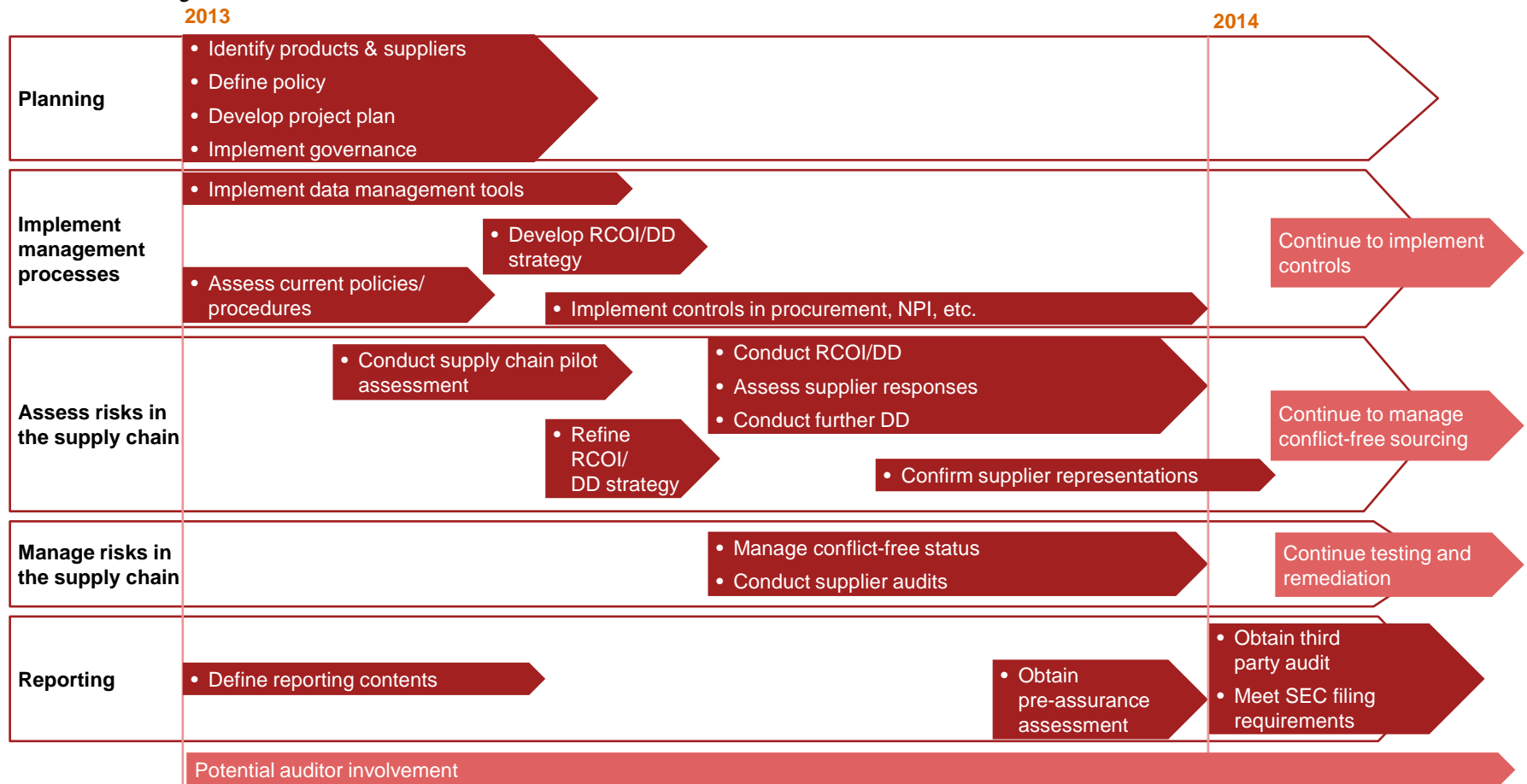
Considerations for leveraging technology applications when conducting conflict minerals compliance activities

- Consider long-term solution vs. short-term band aids
- Go beyond the loudest voice/best marketing to proven successes
- Consider vendor viability – often vendors are new; how long will they be around
- Evaluate the tools you already have
- Move process and technology hand-in-hand
- No silver bullet solution - technology won't solve a process problem

No one tool is currently available that supports end-to-end Conflict Minerals solution requirements

Implement a due diligence program which will both detect and prevent conflict minerals

Develop a flexible and scalable approach that focuses on building supply chain maturity



Status of legal challenge

A judgment will not be made until late 2013 at the earliest.

Therefore, companies should not wait to begin.

A legal challenge to the conflict minerals rule was originally filed with the US Court of Appeals. It was recently transferred to a lower court due to a legal technicality, which could delay the decision. In addition, because the decision will now be made by a lower court, the verdict could be appealed, causing an even longer delay in final resolution of the matter. An initial ruling is not expected until later in 2013, and final resolution is unlikely before 2014.

The basis for the litigation is multifaceted. Despite another Dodd-Frank rule being successfully challenged in the courts, this rule is different. Companies should not presume the legal challenge will be successful, or expect the SEC to delay the effective date of the rule if it withstands the legal challenge.

Conflict Minerals compliance program guiding principles

Lessons learned from our experiences assisting our clients design and implement their Conflict Minerals compliance programs

1 – Take a broad view

2 – Avoid absolutes

3 – Establish a cross-functional team

4 – Leverage other efforts

5 – Focus on supplier engagement

6 – Don't rely only on supplier reports

7 – The framework is only a framework

8 – Consider engaging an auditor early

9 – Focus on process and progress

10 – Technology enables, but is no silver bullet

11 – Keep the end in mind

12 – Monitor the issue

Thank you

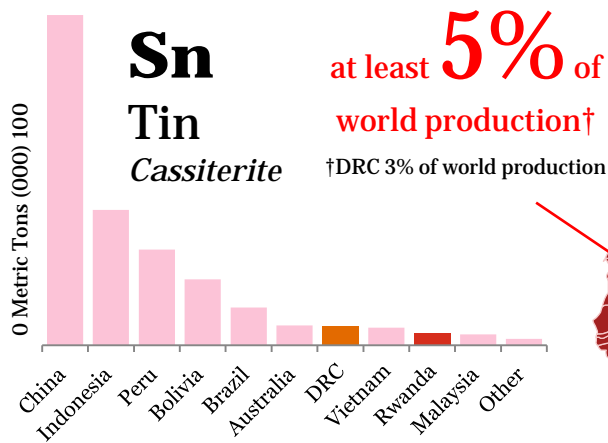
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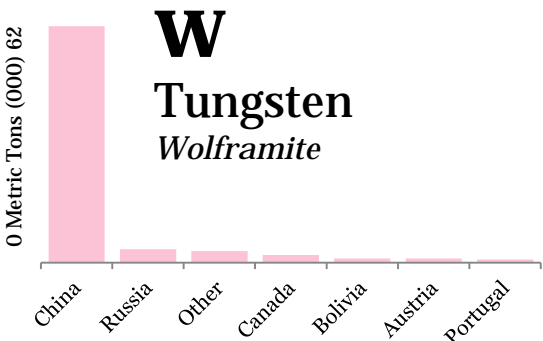
Certain topics discussed in this publication have not yet been fully addressed publicly by the SEC or the SEC staff. Accordingly, the information provided herein is preliminary and is subject to change. PwC will continue to monitor the interpretive guidance provided by the SEC and the SEC staff, and will update the questions/responses as more information becomes available.

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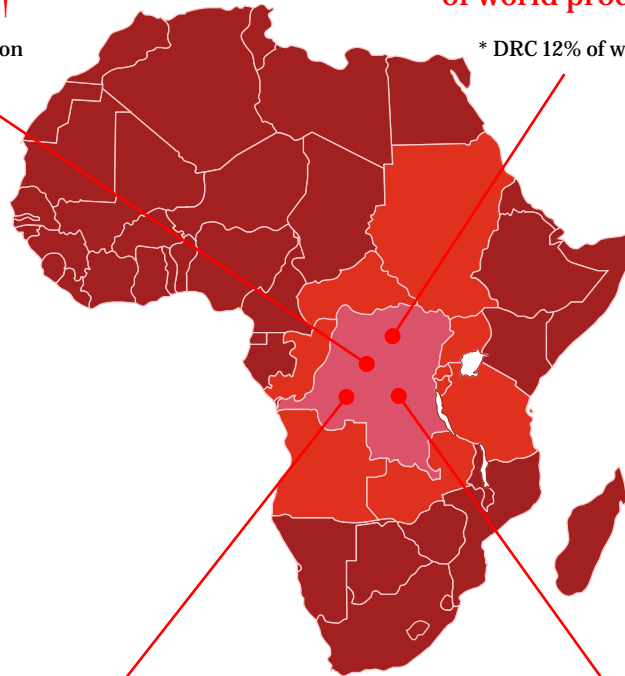
Estimated mine production of 3TG in the DRC and covered countries in 2012



Used in solders for joining pipes and circuits, plating of steel and alloys (bronze, brass, pewter)

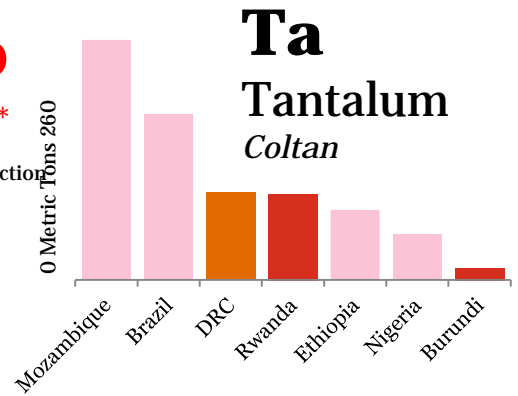


Used in metal wiring, electrodes, electrical contacts, heating, and welding applications

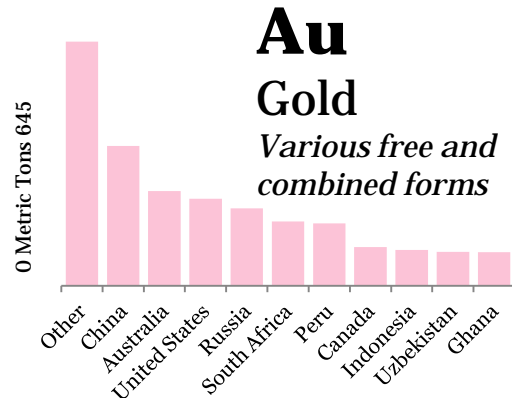


at least **26%** of world production*

* DRC 12% of world production



Used in capacitors (in most electronics), carbide tools, and jet engine components



Used in capacitors (in most electronics), carbide tools, and jet engine components

Covered Countries: Angola, Burundi, Central African Republic, Congo Republic, Rwanda, Sudan, Tanzania, Uganda, Zambia
 Source: U.S. Department of Interior U.S. Geological Survey, Mineral Commodity Summaries, January 2013

Challenges to Implementation for Conflict Minerals Compliance

Room for interpretation

- “Contract to manufacture”
 - Despite additional guidance, what constitutes “sufficient influence” has been left to the issuer
 - Need to strike a balance between meeting minimum threshold required for compliance versus the risk of being singled out by NGO’s for not doing enough
- Necessary for functionality
 - Companies have to decide if 3TG is “necessary for functionality” of their products
- Necessary for production
 - While necessary for production has largely been de-scoped, presence of trace quantities of 3TG in the product that has been used in production is in-scope
- Threshold for declaring conflict free
 - All suppliers need not respond before an issuer can determine if minerals are outside the DRC or whether the minerals are conflict free
- Concluding recycled material
 - Unclear as to what proof an issuer need to accept a supplier’s assertion that the 3TG material was recycled

RCOI and due diligence challenges

- Significant task for issuers with large number of production suppliers
 - Strategy approach – selective versus “all-in”
 - Resale programs
 - Directed supplier programs
 - Service parts
- The SEC Rule does not provide practical guidelines on how to go about conducting RCOI
 - Industry associations left to fill in vacuum
- Getting overseas suppliers to respond to queries
 - No legal requirement for suppliers to identify smelters
- Slow progress on Conflict Free Smelter (CFS) program
 - No CFS certified Tungsten smelter yet
 - Not clear if majority of 3TG smelters will be certified conflict free in 2 years