



# Enhesa Open Forecaster Review Call

Global EHS Regulatory  
Developments

June 2020



Who is Enhesa?

# Enhesa Enterprise

Global Compliance, Local Knowledge, Flexible Technology Enablement



The infographic features a stylized world map in the background. On the left, a vertical bar is composed of colored segments: blue, green, yellow, and orange. On the right, a circular logo contains the Enhesa brand mark and the text 'enhesa.'. The central text is as follows:

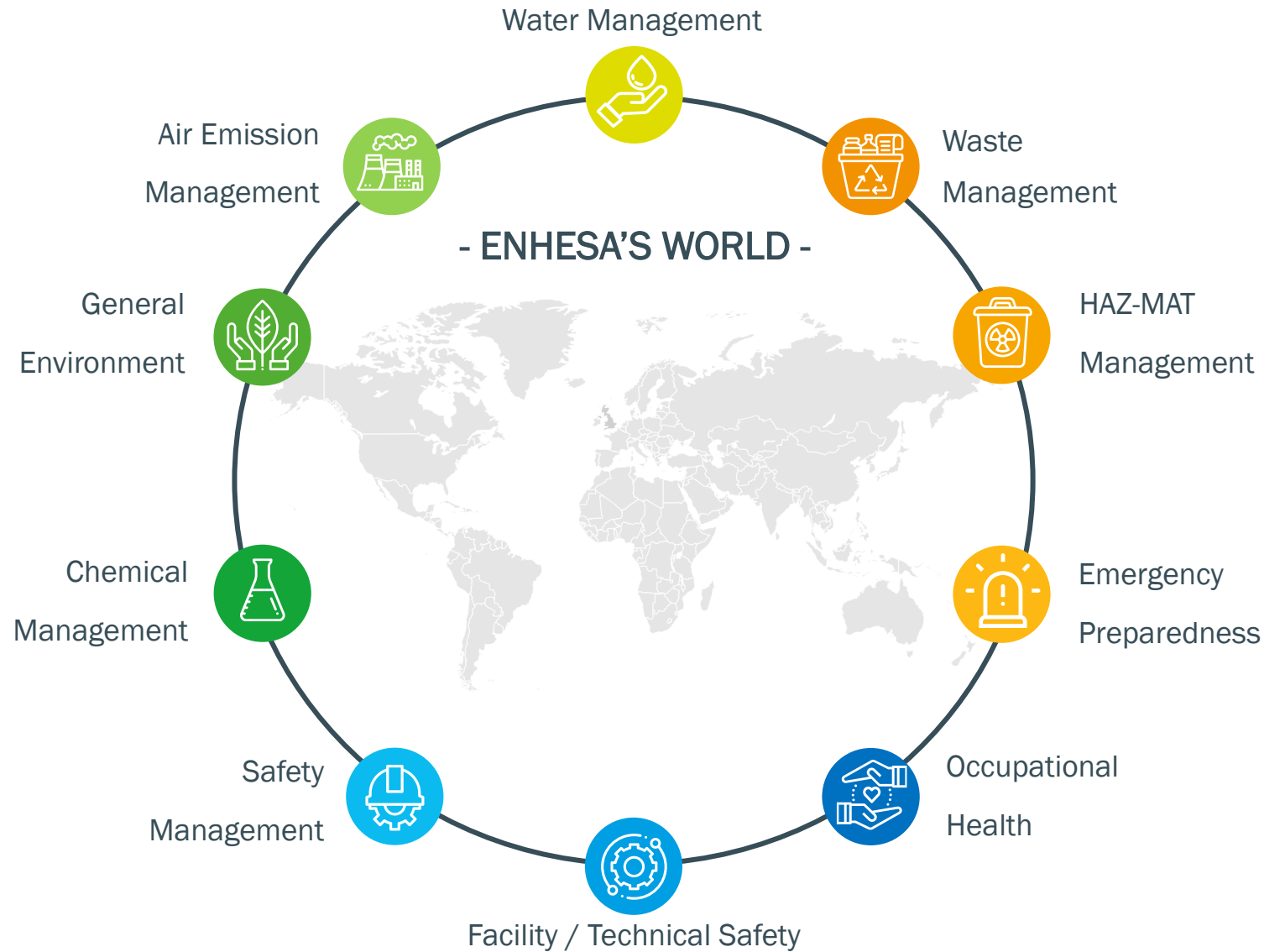
**+300** jurisdictions worldwide

**+30** local languages

To protect what we most care about,  
**let's run compliance true to life.**

# Areas of Expertise

Look at the EHS world in a completely standardized way wherever you are located.



# We are a unique combination of Content, Tools and Services



Standardized, Organized,  
Quality Global **Content**



Consolidated Enhesa  
**Tools** & Dashboards.  
Integration with leading  
platform providers



In-House Expertise.  
Engage additional and as-  
needed regulatory  
support from in-house  
Enhesa regulatory **Experts**

# Enhesa Regulatory Forecaster

- Understand financial and resource implications
- Understand Business Impact of Regulatory Issues
- Integrate EHS Compliance into Culture
- Proactively prepare for Regulatory Changes & Emerging issues



# What do you get?



Monthly Email Alerts



Detailed Analytical Summary



Issues Ranking



Ability to Assign, Annotate and Rank



Company Specific Impact

# Today's Host

John Bez

Expert Support Services Manager  
at Enhesa





# Today's Subject Matter Experts:

## EHS Regulatory Consultants at Enhesa



Abi. O.  
Laniyan



Sunita  
Paudyal



Ramon  
Domenèch  
Aldomà



Ulrike  
Steiger



Elaine Ye



Silvia  
Barlassina

# Today's Subject Matter Experts: EHS Regulatory Consultants at Enhesa



Elise  
Saade



Yujing Pan



Tamlyn  
Jayatilaka



Paula  
Galbiatti  
Silveira



Taylor  
Murphy

# Agenda



1. **South Africa**
2. **India**
3. **Ecuador**
4. **Germany**
5. **China**
6. **European Union**

# Agenda



**7. UAE – Abu Dhabi**

**8. Japan**

**9. Australia**

**10. Brazil**

**11. United States**

# South Africa

## Facilities that undertake essential operations must designate a COVID-19 compliance officer

- On 29 April 2020, the Minister of Cooperative Governance and Traditional Affairs published the Disaster Management Act, 2002; Regulations Issued in Terms of Section 27(2) of the Disaster Management Act, 2002.
- The Regulations apply as of 1 May 2020 and for the duration of the national state of disaster (declared on 15 March 2020).
- The Regulations apply to all facilities permitted to operate during the national state of disaster, including manufacturers of chemicals and pharmaceuticals, and mining operators.



# South Africa

## Facilities that undertake essential operations must designate a COVID-19 compliance officer

- To operate in compliance with the Regulations, your company must:
  - Designate a COVID-19 compliance officer;
  - Implement a plan to phase-in employees' return to work; and
  - Develop measures to ensure workplace adherence to social distancing and hygiene protocols.



# South Africa

## Facilities that undertake essential operations must designate a COVID-19 compliance officer

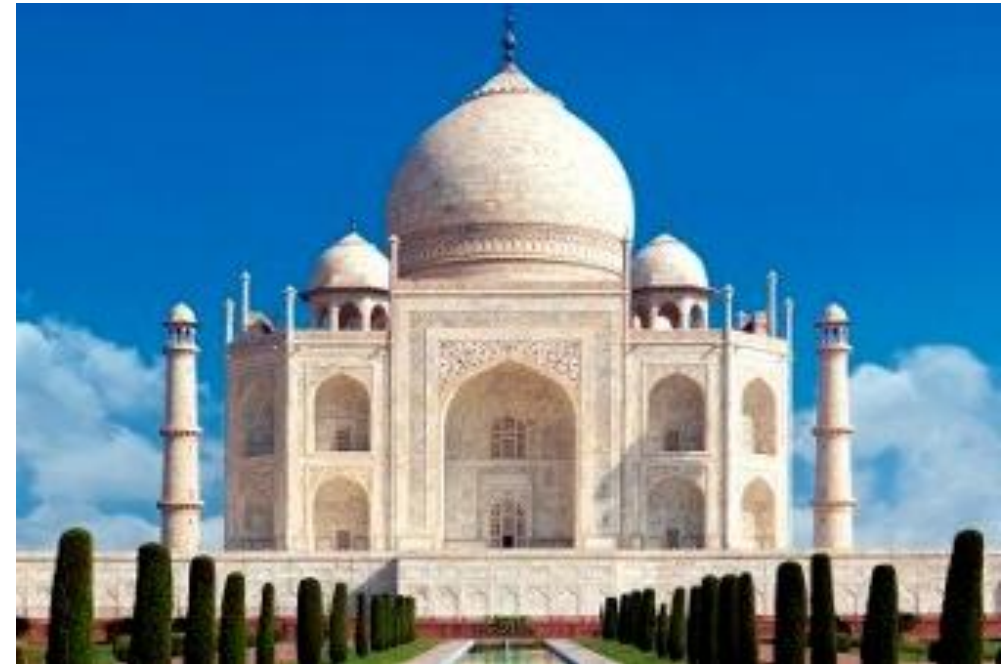
- If your company carries out mining activities, it must, among other requirements:
  - Implement a rigorous screening and testing programme for employees returning to work;
  - Provide quarantine facilities for employees who test positive for COVID-19;
  - Submit testing data to the appropriate authority;
  - Make arrangements to transport South African employees from their homes to their respective areas of operations; and
  - Intensify the monitoring and impact assessment of seismicity through the Council for Geoscience with immediate effect.



# India

**Manufacturing and chemical industries resuming their operations after being shut down for a significant period must undertake stricter health and safety assessment as per the guidelines issued by the NDMA**

- On 9 May 2020, the National Disaster Management Authority published mandatory Guidelines for restarting manufacturing industries after lockdown. The Guidelines have been in force since the date of publication.
- The Guidelines apply to factories and facilities involved in chemicals manufacturing, handling, and storing.
- The main objective of the guidelines is to serve as a checklist for assessing health and safety measures prior to resuming operations for manufacturing facilities where dangerous machinery equipment and hazardous chemicals are in use.





# India

**Manufacturing and chemical industries resuming their operations after being shut down for a significant period must undertake stricter health and safety assessment as per the guidelines issued by the NDMA**

- If your facility manufactures, handles, or stores chemicals, it must, among others:
  - Ensure that safety protocols for handling chemicals, machinery, and equipment are in place and reviewed;
  - Carry out inspection of all equipment and machinery in accordance with the safety protocols and a Safety Audit of the entire unit;
  - Verify and confirm the chemical stability of HAZMAT Chemicals before using them for any processes; and
  - Carry out a trial testing of industrial process before full-fledged production is initiated.
- In addition, your company, after resuming its operations, must:
  - Disinfect common areas such as lunchrooms and canteens every two to three hours;
  - Measure the body temperature of all employees at the facility entrance gate; and
  - Not allow to report to work any employee that has COVID-19 symptoms.

# Ecuador

## Draft law proposed that would regulate and legalize teleworking

- In April 2020, members of the National Assembly proposed a Draft Law that, if approved, would regulate, for the first time, teleworking in Ecuador. The Draft Law would affect all companies.
- The Draft Law would define teleworking as a form of work organization, which consists of carrying out remunerated activities or providing services using information and communication technologies as a support for the contact between the worker and the company, without requiring the physical presence of the worker at a specific site of work.
- The Draft Law would also establish provisions on location and on the right to disconnect.



# Ecuador

## Draft law proposed that would regulate and legalize teleworking

- In addition, the Draft Law would require employers to:
  - Provide the necessary equipment for the development of teleworking; and
  - Report every teleworking situation to the labor authority.
  
- Your facility should be aware of the proposed teleworking requirements. If the Draft Law is finally approved, the labor authority will issue secondary regulations with further information on how your company can comply with the requirements of the Draft Law.



# Germany

## Electricity-intensive companies have more time to submit documents for a reduced renewable energy surcharge

- On 28 May 2020, Germany published an Act amending the Act on the Priority of Renewable Sources of Energy and other energy-related requirements.
- Minor changes include, for example, the removal of certain privileges of so-called citizens' energy companies when it comes to participating in auctions to determine payments for onshore wind installations.
- Under the amended Act on Energy Industry, technical grid connection requirements for specific power generation projects apply only from 31 December 2020 (instead of 30 June 2020).



# Germany

## Electricity-intensive companies have more time to submit documents for a reduced renewable energy surcharge

- The most important change impacts electricity-intensive companies and concerns an extended deadline for the submission of certain documents to the BAFA.
- If your company is an electricity-intensive company and intends to apply for a reduction in the renewable energy surcharge for 2021, it should note that it can submit the audited accounts as well as the ISO 50001 certificate (or equivalent) at the later deadline of 30 November 2020 (instead of 30 June 2020). However, to qualify for a reduction in 2021, your company still has to submit its application electronically by the usual deadline of 30 June 2020.



# China

## Facilities generating particulate matters must comply with analytical monitoring requirements regarding the sources of particulate matters

- On 9 May 2020, the Ministry of Ecology and Environment published the Technical Guidance on Analyzing the Source of Particulate Matter.
- The Guidance applies since 9 May to all facilities generating particulate matters (PMs) from fixed sources, mobile sources, or open-sources.
- The requirements include, for example:
  - Pollution source sample collection;
  - Environmental receptor sample collection;
  - Sample management;



# China

**Facilities generating particulate matters must comply with analytical monitoring requirements regarding the sources of particulate matters**

- PM monitoring project selection and analysis methods; and
  - Quality assurance and control measures for the whole process of PM sample collection, storage, preparation, and analysis.
- If your facility generates PMs from the referred to sources, it must comply with the analytical monitoring requirements specified in the Technical Guidance on Analyzing the Source of Particulate Matter.



# Let's Take a Poll

1. How does your company primarily track regulatory changes? (select all that apply)

- A. Local inhouse legal team
- B. Local inhouse EHS team
- C. Local consultancy firms
- D. EHS software and platforms
- E. Other





# European Union

## The harmonised standard for the technical documentation required for assessing materials, components and electrical and electronic equipment (EEE) under the RoHS 2 Directive has been updated

- On 18 May 2020, the European Commission published the harmonised standard for the technical documentation required for assessing materials, components and EEE drafted in support of the RoHS 2 Directive.
- Although the application of the harmonised standard is not mandatory, manufacturers of materials, components and EEE can decide to comply with it to benefit from a presumption of conformity with the requirements of the RoHS 2 Directive.



# European Union

**The harmonised standard for the technical documentation required for assessing materials, components and electrical and electronic equipment (EEE) under the RoHS 2 Directive has been updated**

- The new harmonised standard (EN IEC 63000:2018 ) will replace, as of 18 November 2021, the currently applicable harmonised standard (EN 50581:2012).
- If your company manufactures EEE or imports or manufactures chemicals to be used in EEE, it can benefit from a presumption of compliance with the RoHS 2 Directive if it applies the harmonised standard EN IEC 63000:2018 (in place of EN 50581:2012) when developing the required technical documentation.



# UAE – Abu Dhabi

## Companies carrying out activities entailing risk to the surrounding environment subject to stiffer fines and enforcement actions

- On 15 May 2020, the Governor of Abu Dhabi amended Law No. 16 of 2005 concerning the reorganisation of the Abu Dhabi Environmental Agency (EAD). The amendment is in force since 15 May 2020.
- The amendment establishes stiffer fines and enforcement actions for non-compliance with Law No. 16 of 2005.
- The amended fine can now amount up to Dirhams 10,000,000 (approximately USD 3,000,000). Previously, it was set at Dirhams 5,000 (approximately USD 1,200).



# UAE – Abu Dhabi

## Companies carrying out activities entailing risk to the surrounding environment subject to stiffer fines and enforcement actions

- The EAD may also take the following actions:
  - Drawing attention;
  - Issuing a warning;
  - Putting the facility under financial, administrative and technical supervision;
  - Suspending the activity temporarily;
  - Cancelling or suspending the license; and
  - Closing the facility temporarily or permanently.
- In all cases, facilities which do not commit to removing the effects of the violation on the specified date must be aware that the EAD will remove them at the expense of the violator.
- If your company carries out activities that could lead to a number of adverse effects on the environment, it should be aware that it can be subject to stiffer fines and might face more stringent enforcement actions from the Environmental Agency of Abu Dhabi if found to be in non-compliance with Law No. 16 of 2005.

# Japan

## Facilities will become subject to stricter exposure limits for ionizing radiation at the workplace

- On 1 April 2020, Japan amended the Regulation on Ionizing Radiation Hazard Prevention. The Amendment will come into effect on 1 April 2021.
- Impacted operations include, for example:
  - Using X-ray devices or carrying out inspections on such devices when they are generating X-ray;
  - Using equipment for accelerating cyclotrons, betatrons and other charged particles, or carrying out inspections on such equipment when it is generating ionizing radiation; and
  - Handling equipment containing radioactive substances.



# Japan

## Facilities will become subject to stricter exposure limits for ionizing radiation at the workplace

- If your company has workers exposed to ionizing radiation, starting 1 April 2021, it will be required to comply with more stringent exposure limits on the equivalent dose received in the eye lens of such workers. This exposure limit will be lowered to 50 millisieverts (mSv)/year. An additional limit of 100 mSv/5 years will also be added for such exposure.
- Your company must also be aware of the revised method for measuring the external exposure dose of workers received in the controlled area, as well as the revised format of the ionizing radiation medical examination result report.



# Australia

## **Australian Industrial Chemicals Introduction Scheme begins 1 July 2020 for chemical importers and manufacturers, with early regulatory changes already in effect**

- The Industrial Chemicals Act 2019 will enter into force on 1 July 2020. This law is the foundation for a new regulatory scheme for the importation and manufacture of industrial chemicals in Australia (Australian Industrial Chemicals Introduction Scheme – AICIS).
- The new framework will require introducers to categorise their introduction into 1 of 6 categories (currently 22): listed, exempted, reported, assessed, commercial evaluation, and exceptional circumstances.
- Companies will still need to register and pay a registration fee each year.



# Australia

## Australian Industrial Chemicals Introduction Scheme begins 1 July 2020 for chemical importers and manufacturers, with early regulatory changes already in effect

- Other changes in AICIS include a ban on the use of new animal test data for ingredients used only in cosmetics and the introduction of a new approach for confidential business information.
- Registrations and certificates will be automatically transferred under AICIS, while permits will be transferred for a temporary period.
- All introducers will be required to submit an annual declaration to AICIS, regardless of introduction category. Information that will need to be included in this declaration is set out in the Industrial Chemicals (General) Rules 2019.





# Australia

## **Australian Industrial Chemicals Introduction Scheme begins 1 July 2020 for chemical importers and manufacturers, with early regulatory changes already in effect**

- Other key changes include, for example:
  - A ban on the use of new animal test data for ingredients solely used in cosmetics;
  - Introduction of a new approach to the treatment of confidential business information, so that companies can apply to AICIS to partially mask the proper name or specific end use of an industrial chemical; and
  - The possibility for assessment certificates to be refused or reconsidered/cancelled on the basis that AICIS is “not satisfied that the risks to human health or the environment from the introduction and use of the industrial chemical can be managed”.
- If your company manufactures or imports industrial chemicals, from 1 July 2020 it is required to comply with the AICIS.

# Let's Take a Poll

2. For which regions does your company struggle to obtain clear information on regulatory changes? (select all that apply)

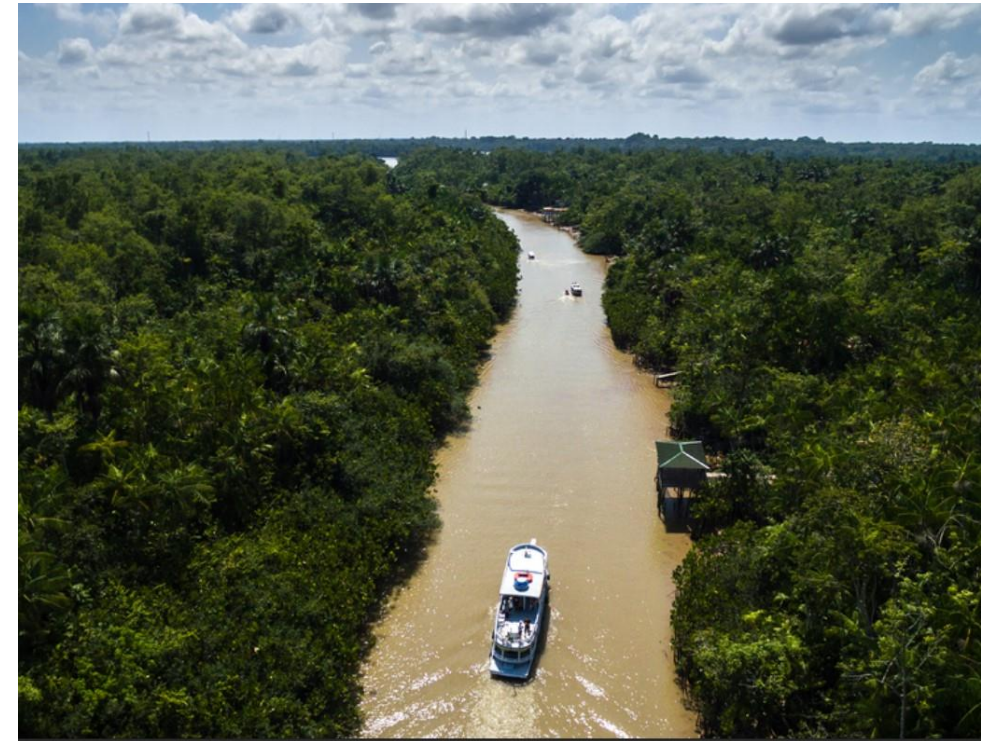
- A. US and Canada
- B. Latin America
- C. Europe
- D. Middle East and Africa
- E. Asia and Oceania



# Brazil

## Companies not providing personal protective equipment (PPE) free of charge for employees could be subject to sanitary criminal responsibility

- Law Proposal 2.267/2020, presented on 28 April 2020 to the House of Representatives, would add sanitary infractions to Law 6.437/1997, which establishes violations to the federal sanitary legislation and respective sanctions.
- Companies could be subject to sanitary criminal responsibility if they:
  - Do not provide adequate PPE to prevent damage to their employees' health free of charge; and
  - Allow people inside the establishment without PPE, when general measures do not provide complete protection against the risks of accidents and damages to their health and safety.



# Brazil

## Companies not providing personal protective equipment (PPE) free of charge for employees could be subject to sanitary criminal responsibility

- Non-compliance could subject companies to warnings, interventions, interdictions, cancellation of licenses, and fines.
- Furthermore, companies not communicating to the competent sanitary authority the occurrence of any sanitary infraction could be subject to warnings and fines.
- Fines would range from BRL 2,000 to 1,500,000.
- Your company must be aware that, in the future, not providing PPE free of charge to employees could be more strictly enforced under the federal sanitary legislation.



# United States

## Certain chemical manufacturers and importers may qualify for the small manufacturer exemption to recordkeeping and reporting requirements under TSCA Section 8(a)

- Effective 29 June 2020, different companies may be exempt from reporting and recordkeeping requirements under the amended definition for small manufacturers under the Toxic Substance Control Act (TSCA) section 8(a) and the small manufacturer definition in the Preliminary Assessment Information Rule (PAIR) rule.
- As before, companies manufacturing or importing for commercial purposes more than 25,000 pounds of a chemical substance which is on the TSCA Inventory (or 2,500 pounds under some circumstances) must comply with the reporting requirements under EPA's Chemical Data Reporting (CDR) rule every four years.



# United States

## Certain chemical manufacturers and importers may qualify for the small manufacturer exemption to recordkeeping and reporting requirements under TSCA Section 8(a)

- As before, companies manufacturing or importing for commercial purposes a chemical listed in 40 CFR 712.30 must submit a "Manufacturer's Report—Preliminary Assessment Information" by the date indicated for the chemical in the rule.
- While the main requirements have not changed, the exemptions for "small manufacturers" have been updated for the purpose of the CDR rule and the Preliminary Assessment Information Rule (PAIR) rule, among other reporting and recordkeeping requirements under the TSCA.



# United States

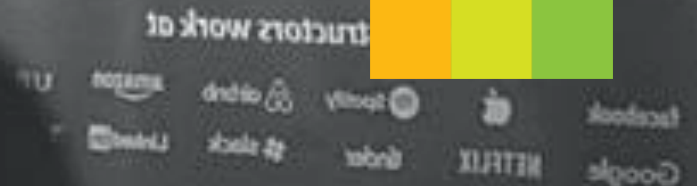
## Certain chemical manufacturers and importers may qualify for the small manufacturer exemption to recordkeeping and reporting requirements under TSCA Section 8(a)

- Under the amendments, to qualify for the small manufacturer exemption, the facility must meet either of the two amended standards.
- Under the first standard, a manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$120 million.
- The manufacturer or importer will not be considered small for the purposes of reporting if the annual production or importation volume of a particular substance at any individual site is greater than 45,400 kilograms (100,000 lbs), unless it qualifies as small under the second standard.
- Under the second standard, a manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$12 million, regardless of the quantity produced or imported.
- If your company manufactures or imports chemical substances, it could be exempt from certain reporting and recordkeeping requirements under Section 8(a) of the TSCA.



## Questions?

Please use the chat to submit any questions at this time. We only have time for a few so we will follow up on any unanswered questions through email.







# Book a discovery call!

Interested in hearing more about our services? Want to know how our products can be applied to your EHS program?

Contact us and request a Discovery Call! We look forward to hearing from you!

[info.enhesa.com/discoverycall](https://info.enhesa.com/discoverycall)

## Contact us!

We look forward to hearing from you if you have any questions! [enhesa.com/contact-us](https://www.enhesa.com/contact-us)



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