PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

PSCI Virtual Supplier Conference 2020 (India)

Session 2 – Environment, Pharmaceuticals in the Environment / Antimicrobial Resistance

Disclaimer: Compliance with local requirements is the responsibility of companies and their local business areas. The information in these presentations is not intended to supersede, take the place of, or conflict with, local government requirements.

Practicalities

- Switch to audio feed only for better connection
- Breaks
- We'll be using Sli.do for Q&As and polls, please follow the link under the Q&A tab on Livestream webpage (Sli.do event code: **#PSCIIndia**)
- Feedback survey

ANTI-TRUST STATEMENT

While some activities among competitors are both legal and beneficial to the industry, group activities of competitors are inherently suspect under the antitrust/anti-competition laws of the US, UK and other countries in which our companies do business. Agreements between or among competitors need not be formal to raise questions under antitrust laws, but may include any kind of understanding, formal or informal, secretive or public, under which each of the participants can reasonably expect that another will follow a particular course of action or conduct. Each of the participants in this meeting is responsible for seeing that topics which may give an appearance of an agreement that would violate the antitrust laws are not discussed. It is the responsibility of each participant in the first instance to avoid raising improper subjects for discussion, such as those identified below.

It is the sole purpose of this meeting to provide a forum for expression of various points of view on topics described in the agenda and participants should adhere to that agenda. Under no circumstances shall this meeting be used as a means for competing companies to reach any understanding, expressed or implied, which tends to restrict competition, or in any way to impair the ability of members to exercise independent business judgment regarding matters affecting competition.

Topics of discussion that should be specifically avoided are:

i. Price fixing;
ii. Product discounts, rebates, pricing policies, levels of production or sales and marketing terms customer and territorial allocation;
iii. Standards setting (when its purpose is to limit the availability and selection of products, limit competition, restrict entry into an industry, inhibit innovation or inhibit the ability of competitors to compete);
iv. Codes of ethics administered in a way that could inhibit or restrict competition;
v. Group boycotts;
vi. Validity of patents;
vii. On-going litigation;
viii. Specific R&D, sales or marketing activities or plans, or confidential product, product development, production or testing strategies or other proprietary knowledge or information.

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

PSCI Environment Sub-Team

RIKKE GADE CHRISTENSEN

HEAD OF SUSTAINABLE PROCUREMENT

LEO PHARMA

ZELIA KRANICH

SUSTAINABLE SOURCING ASSOCIATE DIRECTOR

MERCK & CO., INC., (MERCK SHARP & DOHME OUTSIDE THE UNITED STATES AND CANADA)

AGENDA

Introduction to the Environment Sub Team

About the sub team

PSCI Principles on the Environment

Workstreams

Maturity Model

Supplier environmental training

Speaker Bio

Rikke Gade Christensen

Head of Sustainable Procurement, LEO Pharma

- Rikke has been the Head of Sustainable Procurement at LEO Pharma for the last 4 years. She joined LEO Pharma 6 years ago to formalise processes in relation to supplier sustainability and is currently Member of the Climate task force there. This year Rikke started supporting the PSCI Environment sub-team as a co-lead, mainly for the data collection workstreams.

Speaker Bio

Zelia Kranich

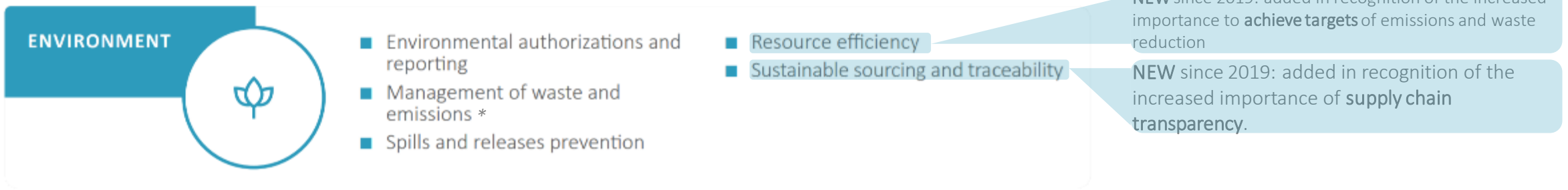
Sustainable Sourcing Associate Director, Merck & Co., Inc., (Merck Sharp & Dohme outside the United States and Canada)

- Zelia is the Sustainable Sourcing Associate Director at Merck & Co., Inc, where she manages supplier environmental sustainability engagement and the procurement process globally. Zelia has over 25 years' experience in the Environmental field, including managing Estee Lauder and Pitney Bowes Environmental Compliance and Sustainability programs globally. Together with Rikke, she leads the PSCI Environment sub-team, particularly around supplier capacity building and training.

About the sub-team

89 *members from* 39 *PSCI member companies*

Responsibilities of the sub-team



**Includes "managing the release of Pharmaceuticals into the Environment"*

Update of PSCI Principles

Previous version

Environment

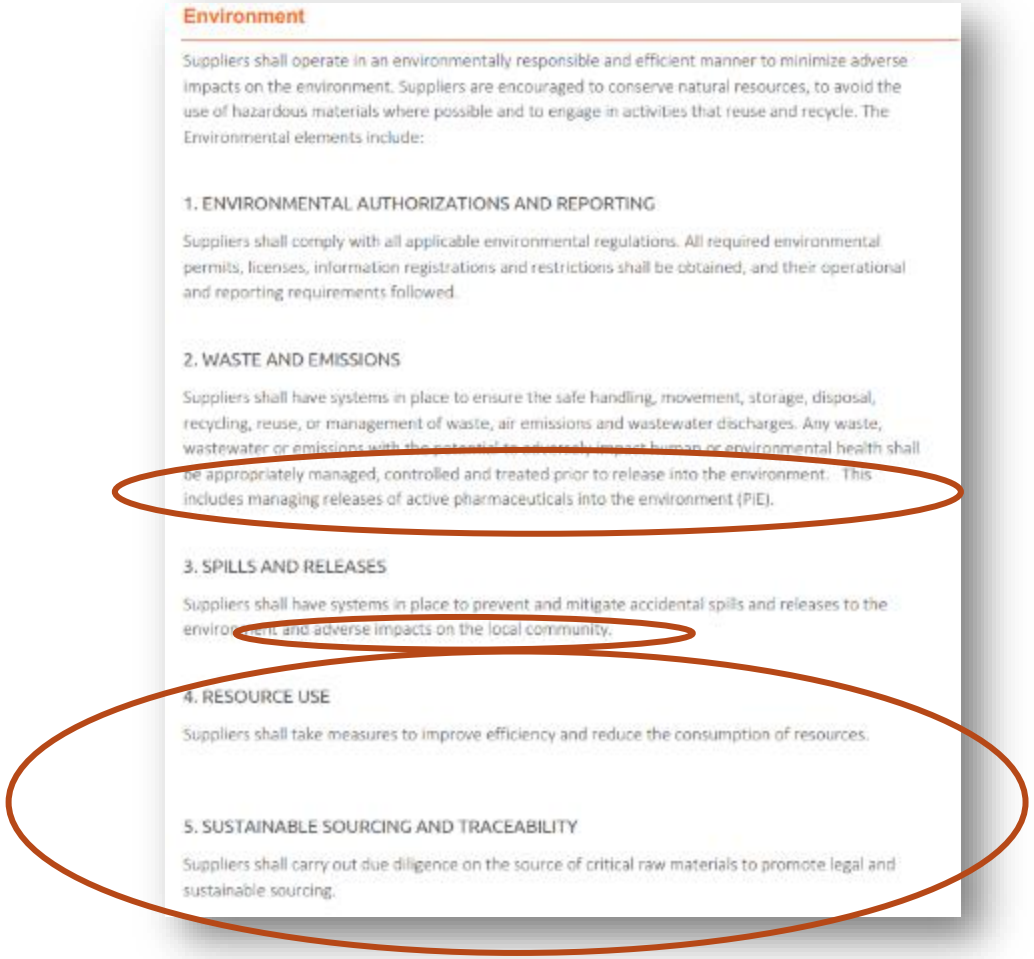
Suppliers shall operate in an environmentally responsible and efficient manner to minimize adverse impacts on the environment. Suppliers are encouraged to conserve natural resources, to avoid the use of hazardous materials where possible and to engage in activities that reuse and recycle. The environmental elements include:

1. Environmental Authorizations
Suppliers shall comply with all applicable environmental regulations. All required environmental permits, licenses, information registrations and restrictions shall be obtained and their operational and reporting requirements followed.

2. Waste and Emissions
Suppliers shall have systems in place to ensure the safe handling, movement, storage, recycling, reuse, or management of waste, air emissions and wastewater discharges. Any waste, wastewater or emissions with the potential to adversely impact human or environmental health shall be appropriately managed, controlled and treated prior to release into the environment.

3. Spills and Releases
Suppliers shall have systems in place to prevent and mitigate accidental spills and releases to the environment.

Updated version effective 01 January 2020



Environment

Suppliers shall operate in an environmentally responsible and efficient manner to minimize adverse impacts on the environment. Suppliers are encouraged to conserve natural resources, to avoid the use of hazardous materials where possible and to engage in activities that reuse and recycle. The Environmental elements include:

1. ENVIRONMENTAL AUTHORIZATIONS AND REPORTING

Suppliers shall comply with all applicable environmental regulations. All required environmental permits, licenses, information registrations and restrictions shall be obtained, and their operational and reporting requirements followed.

2. WASTE AND EMISSIONS

Suppliers shall have systems in place to ensure the safe handling, movement, storage, disposal, recycling, reuse, or management of waste, air emissions and wastewater discharges. Any waste, wastewater or emissions with the potential to adversely impact human or environmental health shall be appropriately managed, controlled and treated prior to release into the environment. This includes managing releases of active pharmaceuticals into the environment (PiE).

3. SPILLS AND RELEASES

Suppliers shall have systems in place to prevent and mitigate accidental spills and releases to the environment and adverse impacts on the local community.

4. RESOURCE USE

Suppliers shall take measures to improve efficiency and reduce the consumption of resources.

5. SUSTAINABLE SOURCING AND TRACEABILITY

Suppliers shall carry out due diligence on the source of critical raw materials to promote legal and sustainable sourcing.

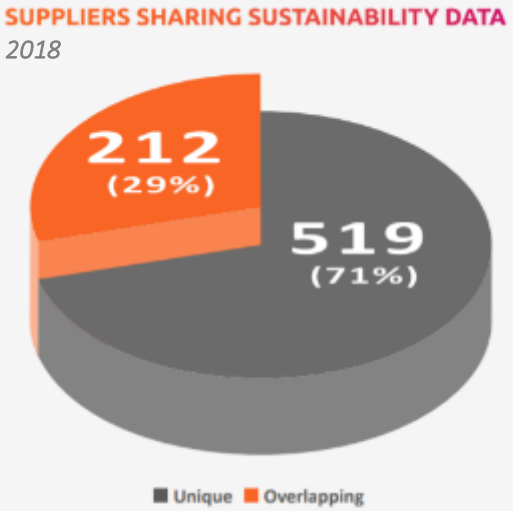
The Principles on the Environment

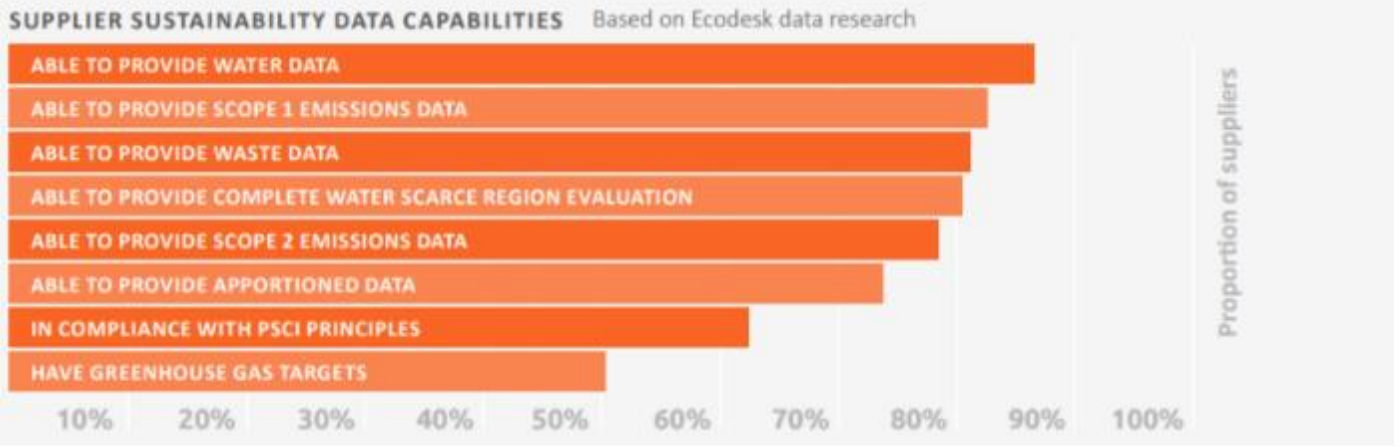
Environmental authorizations and reporting	• Complying with applicable **environmental regulations** (permits, licenses, registrations…) • **Operational and reporting requirements** followed
Management of waste and emissions	• **Systems in place** for safe handling, movement, storage, disposal, recycling, reuse or management of waste/emissions • **Proper management** of waste, air emissions and wastewater discharges with potential adverse effects to humans or environment.
Spills and releases prevention	• **Systems in place to prevent and mitigate** accidental spills and releases to the environment and adverse impacts on local communities.
Resource efficiency	• **Improving efficiency** and **reducing the consumption** of resources.
Sustainable sourcing and traceability	• **Due diligence** on the **source** of critical raw materials to promote legal and sustainable sourcing.

We work in two tracks

Environmental sustainability survey

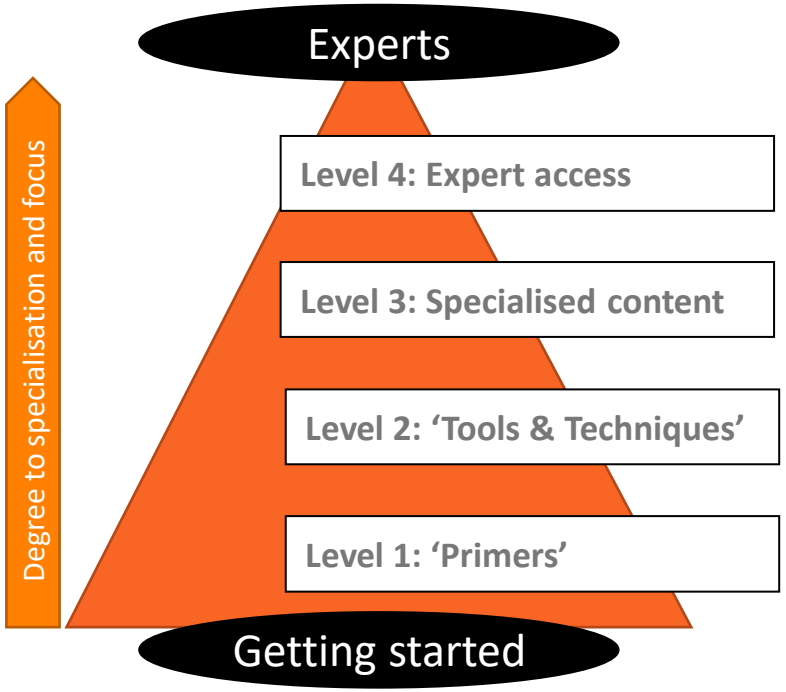
- Supplier survey
  - Establish programme
  - Manage impacts
    - Greenhouse Gas
    - Waste
    - Water
  - Reduce emissions
  - Apportion emissions
- Benefits for suppliers
- Benefits for PSCI members





Training

- 10 categories of specialised areas of knowledge
- 4 levels
- 10 modules level 1 on The Link

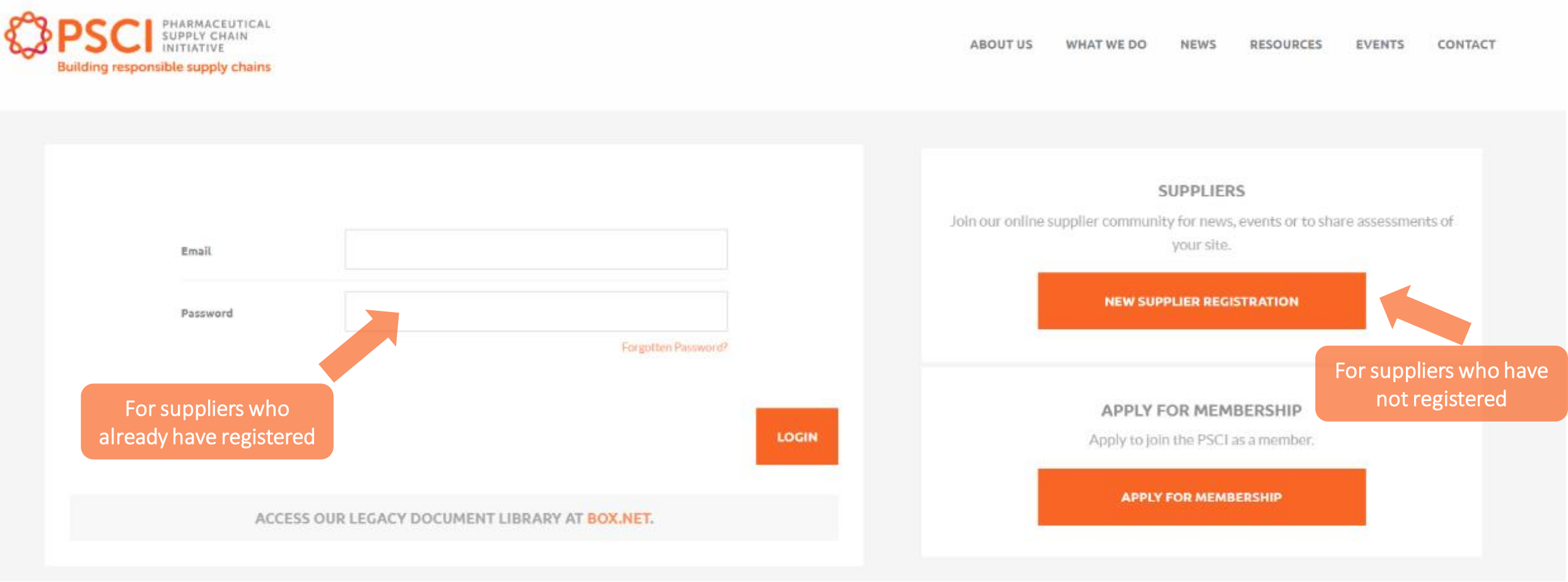


Supplier Environmental Training

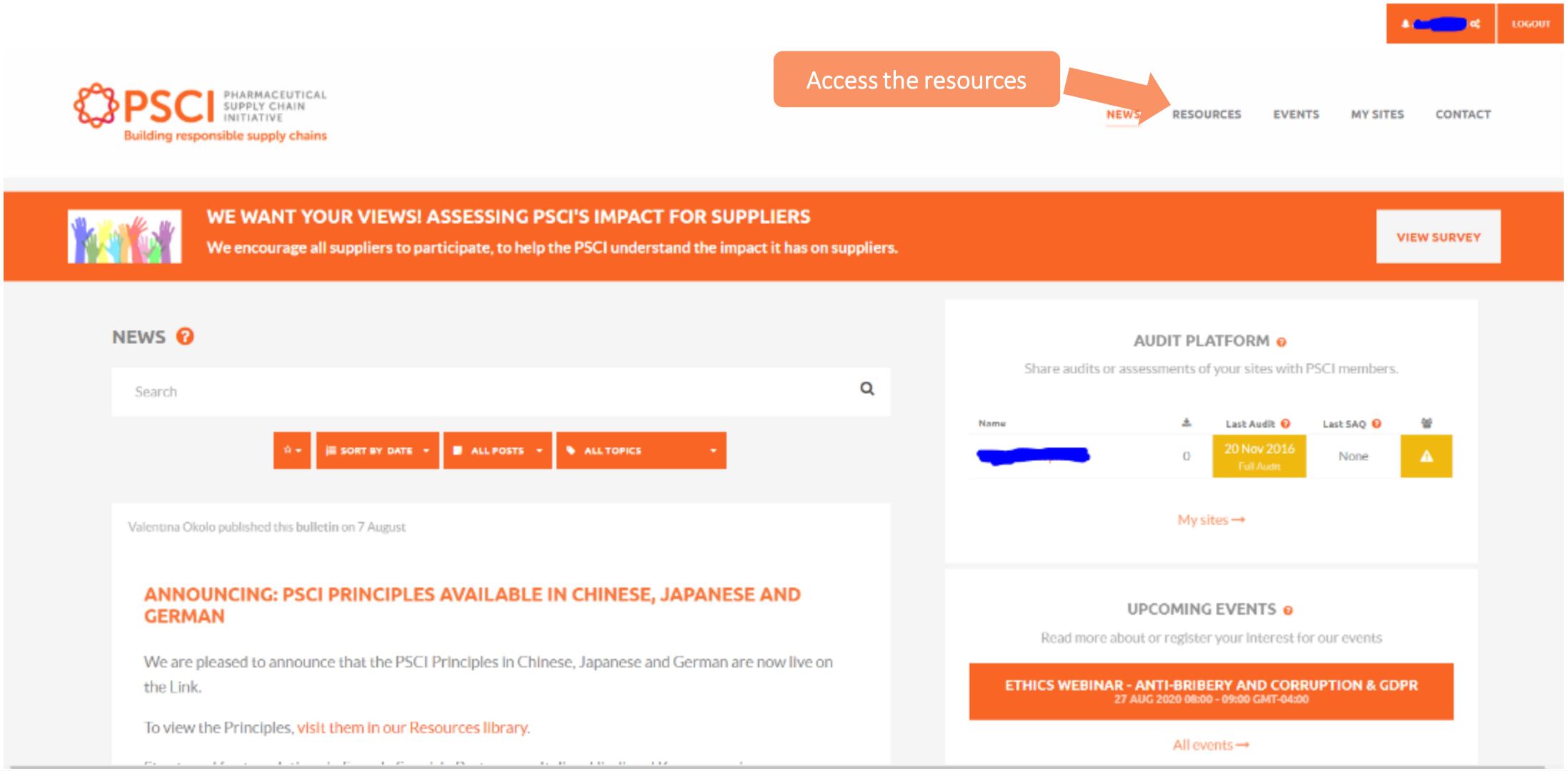
	Level 1: Foundational 'primers' *Downloadable guide for suppliers*	Level 2: Tools & techniques *Online videos and links*	Level 3: Specialised content *'Live' webinars with external input*
The PSCI Principles on Environment	• What are The Principles? • What are the expectations? • Auditing and compliance	• Preparing for audit against The Principles • Case study exemplars	• Customer expectations – beyond The Principles
Environmental Management	• Writing Environmental policy • Basic of an EMS • Measuring performance	• Standards and certification • Setting goals and targets	• Developing Science Based Targets
Compliance and Prevention	• Understanding legislation & responsibilities • Safe operating procedures • Managing a spill or release	• What happens when it goes wrong? • Best practice leak or spill control	• Real time monitoring and citizen science
Climate change	• What is Climate Change? • Sources of Greenhouse Gases (GHG) • The basics of measurement	• Calculating your carbon footprint • What is scope 3?	• Developing a carbon strategy
Energy efficiency	• Managing energy • Changing behaviour • Areas for efficiency improvement	• Factory improvements • Renewable energy opportunities	• Renewable energy opportunities
Green logistics	• What are green logistics • Impacts of distribution • Business travel	• Road vs shipping vs air transport • New technology (i.e., electric vehicles)	• Principles of EV100
Packaging	• Types of packaging • Understanding impacts • Plastics	• Recycling opportunities • Rightsizing and optimisation	• Eliminating plastics
Raw materials	• Raw material sourcing • Key issues and materials • Customer expectations	• The important material standards • Understanding raw material traceability	• Conflict minerals
Water	• Water management • Water quality • Using less water	• Understanding your water risks • Measuring water scarcity	• Green chemistry and ZDHC
Waste	• Waste hierarchy • The basics of waste management • Handling hazardous waste	• Writing waste management procedures • Opportunities for reuse or recycling	• Zero waste to landfill
PiE & AMR	• Importance of managing API releases • Developing company standards & PSCI expectations on PiE/AMR • Manufacturing API discharge limits	• Risk assessment techniques for PiE/AMR • Techniques for reducing API losses • Liquid/solid waste releases & zero liquid discharge • Wastewater treatment (WWT) options	• WWT plant operation & maintenance • Confirming API releases and/or WWTP effectiveness with analysis • Compliance reviews & preparing for PiE/AMR audit

Level 4 (Expert access) will be agreed on a case by case basis as discussions and content are likely to be very specific.

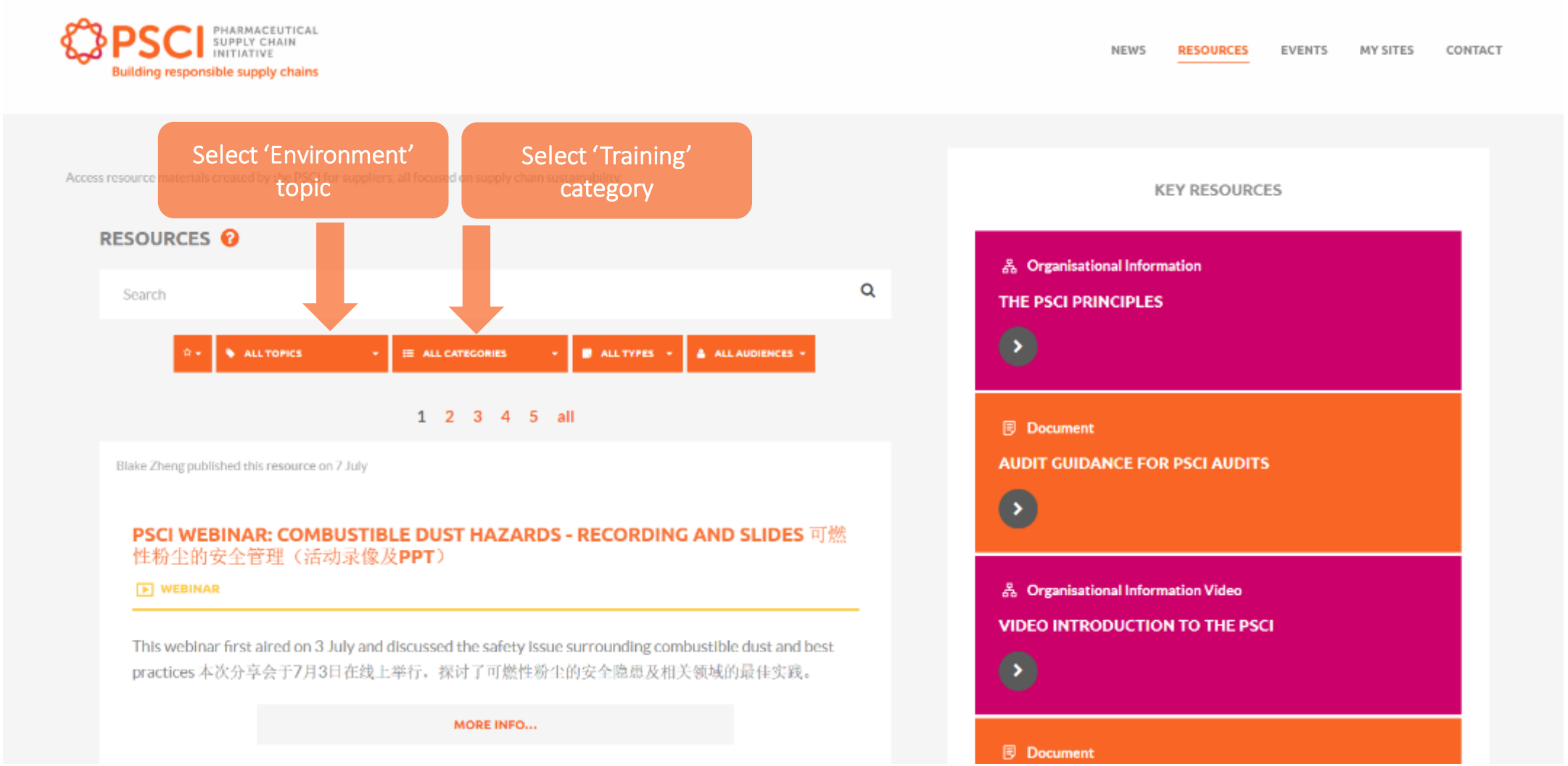
Accessing the resources



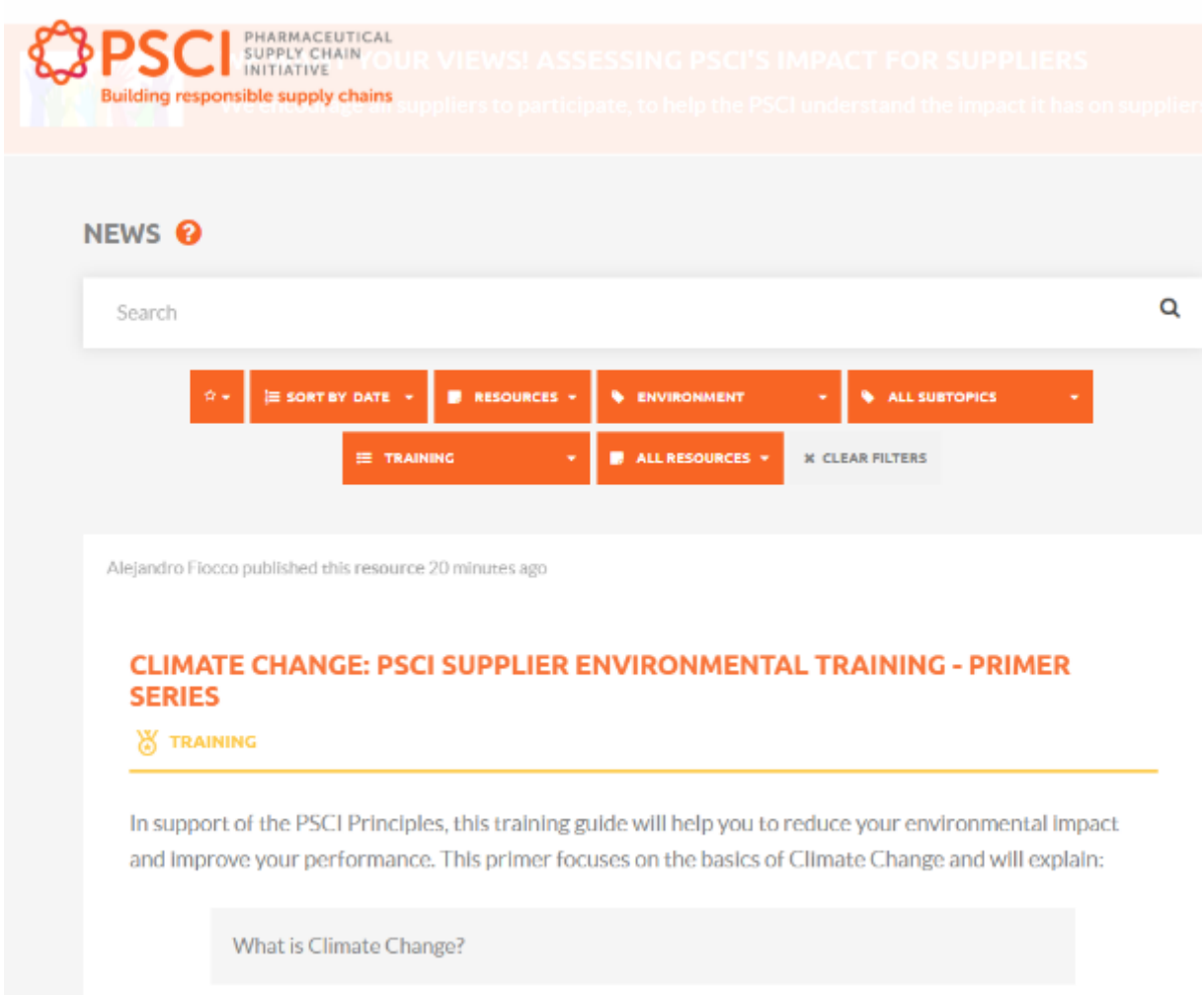
Accessing the resources



Accessing the resources



Accessing the resources



PSCI Common Framework

Starting out	Developing	Implementing	Leading
• Compliance with law • Necessary policies in place • Minimum standards are being met	PLUS • Audits / baselines / risk assessments complete • Key risks and highest impacts identified • Measurement and recording systems in place • Management responsibility has been allocated • Targets and objectives set	PLUS • Processes in place with clear responsibilities for key staff • Employees are aware and trained as appropriate • Targets generally being achieved • Improvement projects • External verification • External partnerships being developed • Public reporting or other transparency • Risks are adequately managed	PLUS • Embedded in culture • External recognition / awards • Taking an advocacy stance • Approach includes whole value chain • External partnerships across industry • Supporting partners / customers to improve. • Sustainability drives innovation • Sustainability leads to differentiation and commercial advantage

Environmental Maturity Model – Example Draft

- Several groups considering Maturity Models and more likely in future
- Each Model will have different technical content depending on the subject.
- We see the need for a common framework to ensure alignment and consistency

PSCI Principles	Starting out	Developing	Implementing	Leading
Environmental authorisations and reporting				
Waste and emissions				
Spills and releases				
Resource use				
Sustainable sourcing and traceability				

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Taking climate action
(Why it's important and how to do it)

GLYNN ROBERTS

DIRECTOR AND SENIOR PARTNER

CARNSTONE PARTNERS LIMITED

AGENDA

Taking climate action

Evidence to show that the Climate Crisis is real and unavoidable

The commitments of pharma companies and why they are looking towards their suppliers

Demonstrate the business case for climate action

Calculating your greenhouse gas emissions

Five next steps for your business

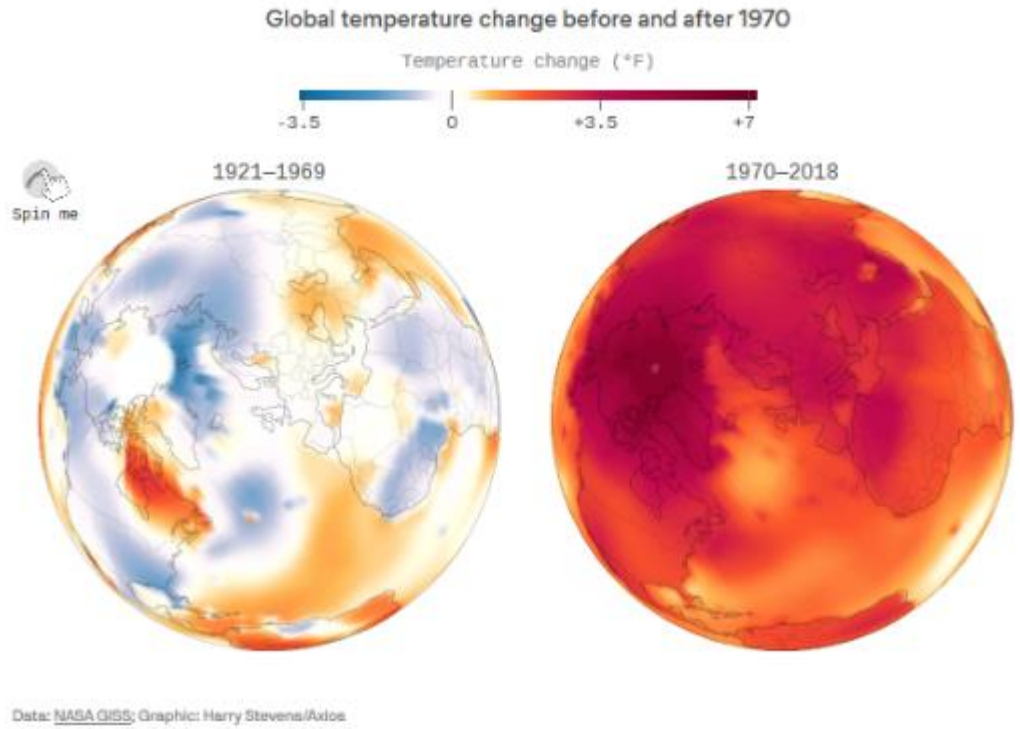
Speaker Bio

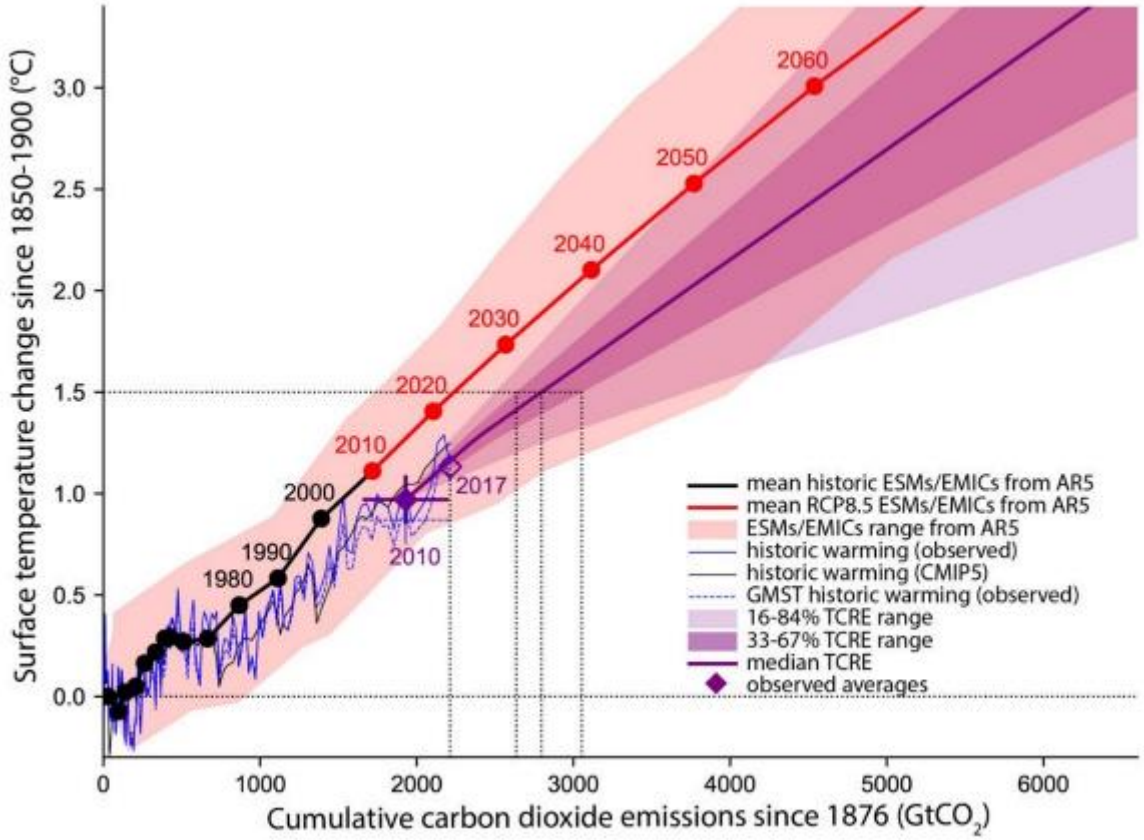
Glynn Roberts

Director and Senior Partner, Carnstone Partners Limited

- Glynn has strong environmental experience; pushing the agenda and helping to strengthen companies' approaches to water stewardship, energy management and climate change. He is also an expert in organisational performance management and reporting, advising a range of clients from global manufacturers to leading UK retail brands.

The data tells us the world is changing….






SW

BRIEF

AstraZeneca pledges to go 'carbon negative' by 2030

Pfizer Implemented More than 4,000 Greenhouse Gas Reduction Projects Since 2000

Commitment to Carbon Neutrality at Takeda

BRIEF

Renewable energy to power all Novo drug production by next year

Bloomberg

Deals

Johnson & Johnson Buying 100 Megawatts of Texas Wind Power

GSK begins to make inroads on supply-chain emissions

The pharmaceuticals multinational has begun giving awards to suppliers that have managed to reduce their energy levels – among other initiatives

The impact of the pharma sector

SCOPE 1

Direct emissions from owned or controlled sources

5.9 Million tonnes

4% reduction since 2016

SCOPE 2

Indirect emissions from the generation of purchased electricity, steam, heating and cooling

6.6 Million tonnes

10% reduction since 2016

SCOPE 3

All other indirect emissions that occur in a company's value chain

91.0

Million tonnes

Understanding the business case

Focus on your scope 1 and 2 emissions: Four key questions

Which activities in my organisation release GHG emissions?	What information should I collect from these activities to calculate my GHG emissions?	How do I calculate my GHG emissions?	How often I track my emissions over and report performance?
• Fuels combustion (e.g. boilers, furnaces or turbines) (Direct: Scope 1) • Consumption of purchased electricity, heat, steam and cooling (Indirect: Scope 2) • Process emissions (e.g. cement, aluminium, waste processing) (Direct: Scope 1) • Owned transport (e.g. trucks, trains, ships, airplanes, cars) (Direct : Scope 1) • Fugitive emissions (e.g. air conditioning and refrigeration leaks, methane leaks from pipelines) (Direct : Scope 1)	• Activity data is information used to calculate GHG emissions from combustion and other processes, for example, this could be litres of fuel consumed by your organisation's vehicles. • Most activity data is easy to obtain, relatively accurate and can be found on bills, invoices and receipts. • It is best to collect activity data by volume or mass (e.g. litres of petrol used) as emissions can be calculated more accurate.	• The most common approach used to calculate GHG emissions is to apply documented emission factors to known activity data from the organisation. • An emission factor is a coefficient which allows to convert activity data into GHG emissions. It is the average emission rate of a given source, relative to units of activity or process/processes. **GHG emissions = Activity Data x Emission Factor**	• The period for which you collect data must suit your internal and external reporting needs. • We recommend that your reporting period should be for 12 months. • Your emissions year should ideally correspond with your financial year. • To help you maintain a meaningful and consistent comparison of emissions over time, you will need to choose and report on a base year.

Sources of emissions factors

- There are many sources of GHG emissions factors. It is best to select the source that is most relevant to your business. These are often produced by local government agencies in your country. The important thing is to be consistent.
- The table below offers some suggestions for factors for common fuels. These are based on information from the GHG Protocol (the 'rule book) and the International Energy Authority (for electricity, which changes based on your national power generation mix)

Fuel	Unity	Emissions factor	Source
Coal	$kgCO_2$/tonne	2,624	GHG Protocol
Natural gas	$kgCO_2/m^3$	1.88	GHG Protocol
Gas/Diesel Oil	$kgCO_2/m^3$	2.67	GHG Protocol
Electricity (China)	$kgCO_2$/kWh	0.62	IEA
Electricity (India)	$kgCO_2$/kWh	0.72	IEA
Petrol	$kgCO_2$/litre	2.27	GHG Protocol
Diesel	$kgCO_2$/litre	2.67	GHG Protocol

Example calculation….

Apex Chemicals makes chemical products used by the pharmaceutical sector. It has a manufacturing site and office. The manufacturing process uses heat to treat and process raw materials, using natural gas and coal fired boilers. Electricity is used to power each site, mainly for lighting and computers, is bought from a local energy provider. When products are made, they are delivered directly to the customer using company owned trucks on the road. There are no other vehicles.

Information relating to fuel and electricity use is collected on an annual basis – from a combination of meter readings, invoices from fuel suppliers and energy bills.

Energy consumption	Annual consumption	Units
Coal	5,600	Tonnes
Natural gas	12,700	m3
Electricity (China)	24,000	kWh
Diesel	55,000	Litres

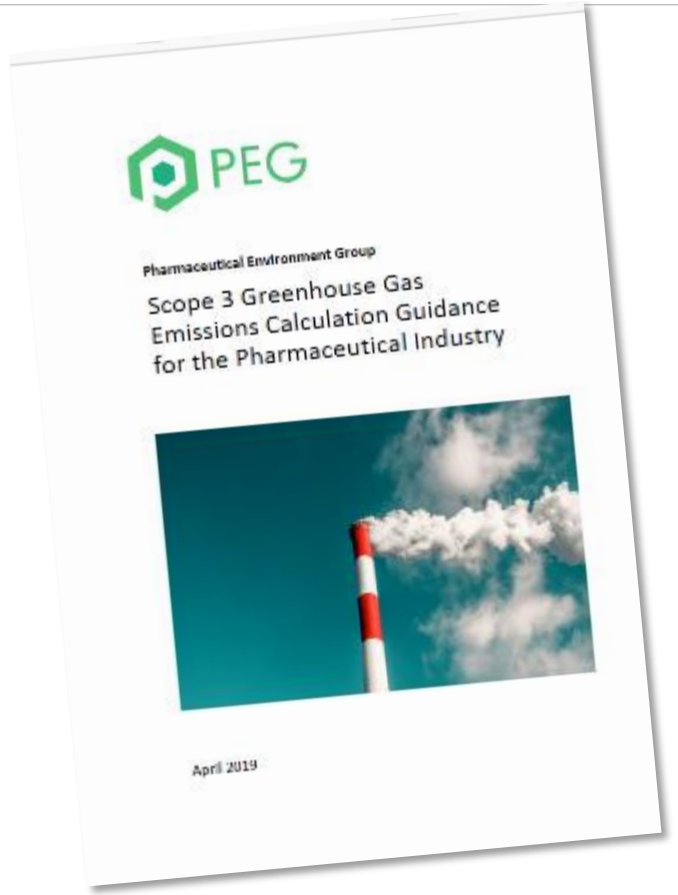
How many tonnes of GHG emissions were emitted last year?

GHG emissions = Activity Data x Emission Factor

Energy consumption	Annual consumption	Units	*Emissions factor*	*GHG emissions $KgCO_2$*
Coal	*275*	Tonnes	2,624	*271,600*
Natural gas	117,555	m3	1.88	*221,003*
Electricity (China)	75,000	kWh	0.62	*46,500*
Diesel	*22,500*	Litres	2.67	*60,075*
			TOTAL	***599,678***

Total annual emissions = 600 tonnes

Sources of information



Principles of GHG accounting and reporting

RELEVANCE:	Ensure the GHG emissions you report appropriately reflect the emissions of your organisation and serves the decision-making needs of users – both internal and external to the organisation.
COMPLETENESS:	Measure and report on all GHG emissions sources and activities from the businesses / operations for which you are collecting GHG. Disclose and justify any specific exclusions.
CONSISTENCY:	Use consistent methodologies to allow for meaningful comparisons of emissions over time. Transparently document any changes to the data, changes in your organisational boundary, methods, or any other relevant factors
TRANSPARENCY:	Address all relevant issues in a factual and coherent manner, keeping a record of all assumptions, calculations, and methodologies used. Report on any relevant assumptions and make appropriate references to the accounting and calculation methodologies and data sources used.
ACCURACY:	As far as can be judged, ensure that your reported GHG emissions data is systematically neither over nor under your actual emissions. Seek to reduce uncertainties in your reported GHG emissions where practical. Achieve sufficient accuracy to enable users to make decisions with reasonable assurance as to the integrity of the reported information

Five steps to GHG reduction

Step 1:
Measure energy use and emissions*:*

Review your gas, electricity and fuel bills to assess how much energy is used each year and from which activities. Convert your energy usage into a carbon footprint, using a globally recognised frameworks, such as the *Greenhouse Gas protocol*.

Step 2:
Identify opportunities to reduce emissions:

Where are the opportunities for you to use less energy or fuel? Can you improve the energy efficiency of your operations or drive less? Can you use renewable energy? Undertake a review or audit of your business to find out.

Step 3:
Set a target:

Based on the opportunities available, set a target to reduce your emissions. Usually at least 10% of your energy can be saved at no or low cost to your business. Secure management support and budget (if needed)

Step 4:
Create an action plan:

Prioritise your actions based on cost and emissions savings. Be clear on the steps you will take based of the opportunities identified.

Step 5:
Engage with your pharmaceutical customers:

Many of these companies will have their own targets and plans. They will be able to offer advice, guidance and support.

Poll – To submit your responses, please go to https://app.sli.do/ and enter the event code: #PSCIIndia

1. **How would you assess the maturity of your Scope 1 & 2 reporting capability?**
   a. Not started: Do not collect any data and need some guidance
   b. Beginning: Can provide basic GHG reporting on an annual basis
   c. Developing: Track and manage GHG data across entire organization; report to one or many GHG collecting organizations
   d. Mature: Track and manage GHGs by facility; actively exploring ways to reduce your Scope 1 & 2 emissions
2. **Do you have a plan to reduce your greenhouse gas emissions?**
   a. No
   b. Yes
   c. Yes, and we have detailed quantitative targets for emissions reduction
3. **Please select the challenges preventing you from reporting your Scope 1 & 2 emissions more frequently?**
   a. Available technology
   b. Employee bandwidth / expertise
   c. Maturity of your ability to collect necessary data
   d. No business benefit / other priorities
   e. Knowledge of how to go about reducing emissions
   f. Other

To ask questions, please go to https://app.sli.do/ and enter the event code: #PSCIIndia

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Sustainable Packaging

ZELIA KRANICH

SUSTAINABLE SOURCING ASSOCIATE DIRECTOR

MERCK & CO., INC., (MERCK SHARP & DOHME OUTSIDE THE UNITED STATES AND CANADA)

VICTOR BELL

US MANAGING DIRECTOR

LORAX EPI

JACQUELINE HOLLANDS

GLOBAL MANAGER, CUSTOMER SUSTAINABILITY SOLUTIONS

MILLIPORESIGMA

AGENDA

Sustainable packaging

Packaging basics and the case for action

Sustainable packaging

Packaging disposal hierarchy

Sustainable packaging initiatives

Case Studies

Speaker Bio

Zelia Kranich

Sustainable Sourcing Associate Director, Merck & Co., Inc., (Merck Sharp & Dohme outside the United States and Canada)

- Zelia is the Sustainable Sourcing Associate Director at Merck & Co., Inc, where she manages supplier environmental sustainability engagement and the procurement process globally. Zelia has over 25 years' experience in the Environmental field, including managing Estee Lauder and Pitney Bowes Environmental Compliance and Sustainability programs globally. Together with Rikke, she leads the PSCI Environment sub-team, particularly around supplier capacity building and training.

Speaker Bio

Victor Bell

US Managing Director, Lorax EPI

- Victor Bell is a Lifetime Certified Packaging Professional with more than 25 years of experience with environmental issues relating to packaging and products. He is a founding member of the Sustainable Packaging Coalition (SPC) and has served on its Executive Committee. He was also a member of the Consumer Goods Forum GPPS project team and served on the US delegation for the development of the ISO standards for packaging design. In April 2018, Victor received the SPC Outstanding Person of the Year Award. Victor frequently works with brand owners, retailers and packaging producers to develop their packaging sustainability goals, and he also provides techniques and tools to track their progress towards established goals.

- Contact information:
  - vbell@enviro-pac.com

Speaker Bio

Jacqueline Hollands

Global Manager, Customer Sustainability Solutions, MilliporeSigma

- Jacqueline Hollands leads and develops MilliporeSigma's initiatives and programs that meet the sustainability needs for customers. She has implemented product recycling options, such as the Biopharma Single-Use Product Recycling Program and the ech2o™ Lab Water Cartridge Recycling Program. Currently she is working on developing innovative recycling solutions for the life science industry.

Different types and functions of packaging

Primary packaging

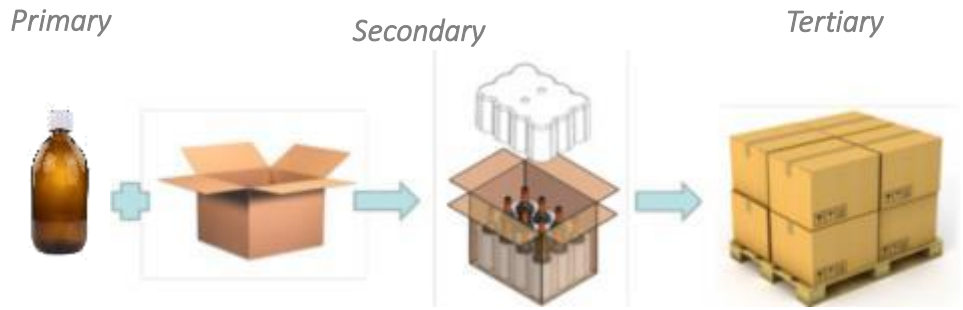
- is the packaging which is in **direct contact with the product**, usually when it is handled by the customer.

Secondary packaging

- encases **multiple quantities** of primary packaging for transit, storage and retail.

Tertiary Packaging

- is used for **transportation and shipping**. Its main purpose is to keep the product safe in transit by protecting the primary and secondary layers of packaging from external influences.



Source (adapted): Packaging system and sustainability (Sustainable Packaging Coalition)

The case for action

Depletion

2x *energy required to produce paper and cardboard, compared to plastic*

42% *of global wood harvest is used for paper products*

324 *litres of water to produce 1 kg of paper*

Pollution

60% *of plastic ended up in landfill or polluting the environment*

8 million tonnes *of plastic escapes into oceans from coastal nations*

400 years *it takes to break down plastic that contain additives to make them stronger and more flexible*

Five actions your business can take now

Step 1:
Check regulatory compliance

Ensure the packaging in your value chain meets the legislative requirements in the countries where it is sourced and disposed. Check all packaging taxes and regulatory filings are up to date.

Step 2:
Packaging sourcing and innovation

Review packaging specifications to determine opportunities for switching to sustainable sources and for recycled and recyclable materials, to develop a more circular flow of packaging.

Step 3:
Waste contractors

Review disposal of packaging waste from your own operations with waste contractors to investigate options for improving recyclability. Set recycling targets and ask for annual reports to track progress.

Step 4:
Eliminate unnecessary packaging

Conduct an audit of packaging used to identify unnecessary packaging used in your processes (including transit packaging) and plan how to avoid its use

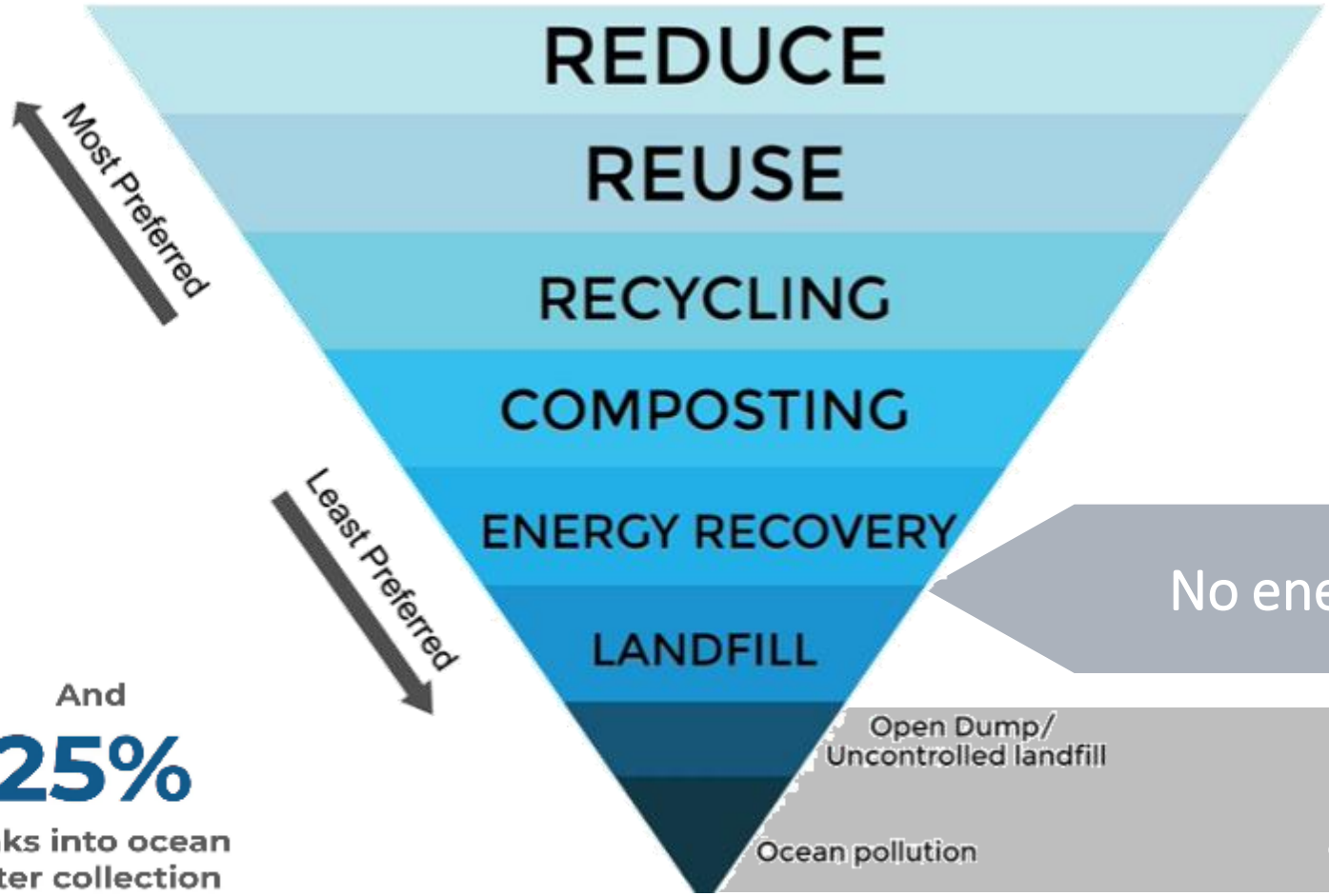
Step 5:
Right-sizing

Work with your customers to explore opportunities for right-sizing the packaging in your shared value chain. This optimization will lead to cost saving opportunities.

Sustainable Packaging Basics

- Easy wins first (ex. non-regulated, previous supplier experience, scalable)
- Reduce packaging size (versus dosage) / eliminate layer or coating?
- Use recycled materials
- Reusable
- Recyclable / ease of recycling
- Environmental certified materials
- Manufacturing process simplification

Packaging Disposal Hierarchy



*Adapted from Zero Waste Europe

Over **80%** of ocean plastic comes from land

And of that, **75%** comes from uncollected waste

And **25%** leaks into ocean after collection

Sustainable Packaging Initiatives – Packaging must still perform!

Recycled Material

- Post-Consumer recycled content (PCR):
  - Designed for Recycled Content Guide

Recyclable

- Mono-materials
- Easy separation
- Larger size
- Recycling claim on package / instructions
- URL to site with recycling directions
- Avoid colorants
- Consider closures, glue, inks, etc.

Reusable and Refillable

- Pallet re-use
- Closed-loop
- Pouches

Alternative / Certified Materials

- Sustainable Aluminum
- Sustainable forest management - FSC, PEFC, etc.
- Bio-based versus petroleum-based
- Avoid unsubstantiated claims of biodegradability
- Eliminate toxic materials / heavy metals

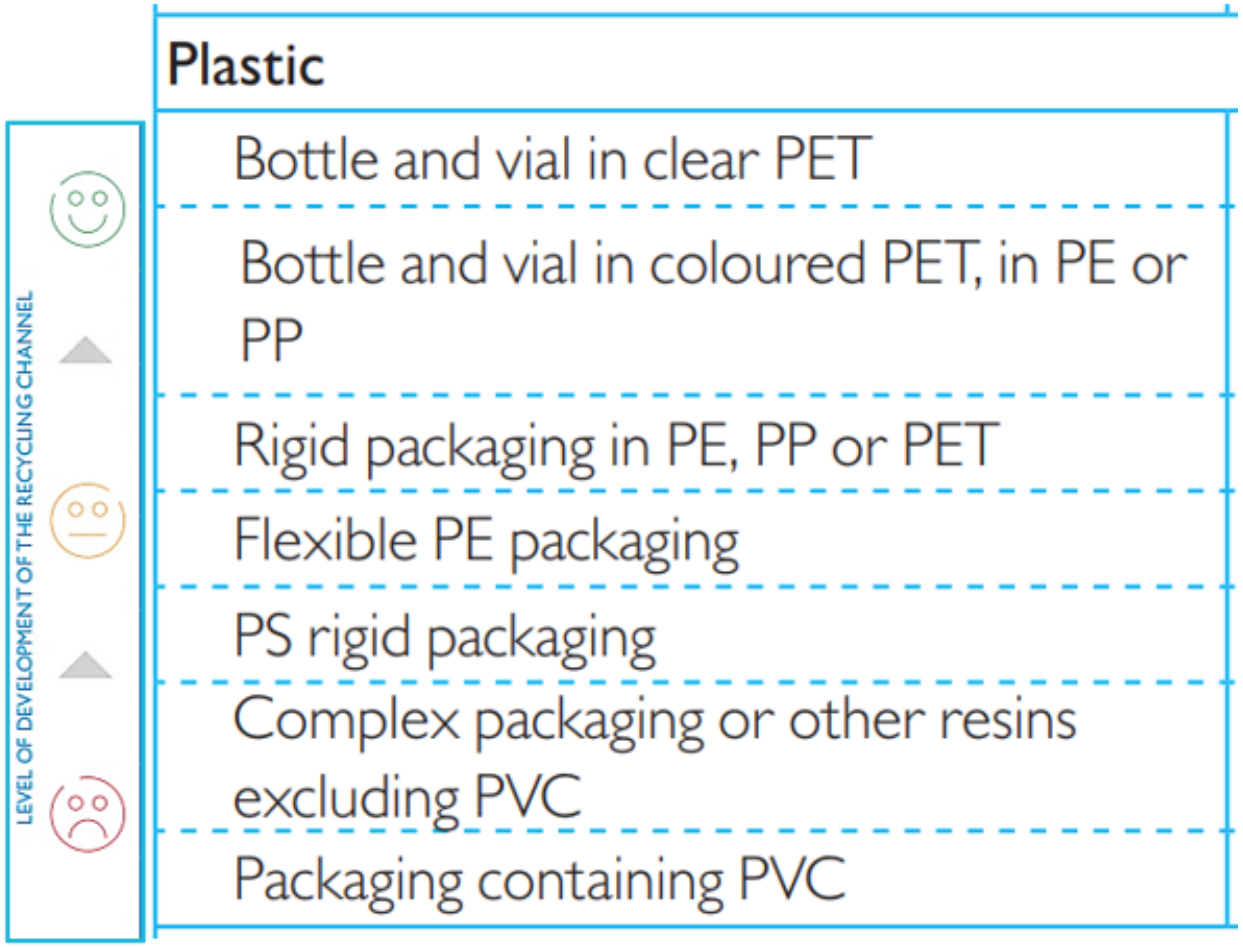
Process Simplification / Material Reduction

- Standardize packaging
- Remove layers
- Avoid inserts
- Reduce unnecessary process steps
- Resource usage reduction – water, energy, etc.
- Source materials locally
- Increase mass / volume per dose
- LCA

Improve recyclability by removing disruptors

- To ensure the recyclability of your packaging, consider moving away from:
  - Black plastic
  - Aluminum on PET blisters
  - Glass bottle with non-metallic cap
  - HDPE with large amounts of EVOH
  - Aluminum can with steel nozzle

Understand the recyclability of different materials



Source: CITEO 2020 rates for recycling household packaging

Tools and platforms

Design	COMPASS® COMPARATIVE PACKAGING ASSESSMENT
Sourcing	RMS; USDA CERTIFIED BIOBASED PRODUCT PRODUCT 95%; FSC MIX From responsible sources FSC® C000000
Material Health	chemsec MARKETPLACE; GREENSCREEN® FOR SAFER CHEMICALS
End-of-life/ Recovery	BPI COMPOSTABLE IN INDUSTRIAL FACILITIES Not suitable for backyard composting. CERT # SAMPLE; Empty & Replace Cap PLASTIC BOTTLE how2recycle.info

Using recycled content improves GHG profile

- Redipoint® GHG Coefficients for using Recycled Content
  kg CO_2 eq per kg of material

Redipoint Coefficients	10% recycled content	50% recycled content	100% recyced content
Glass	**1.051**	0.855	0.660
Metal - Aluminum	**18.178**	10.209	2.240
Paper - Bleached Corrugated	**0.788**	0.666	0.544
Paper - Unbleached Corrugated	**0.749**	0.683	0.617
Paper - Bleached Paperboard, coated	**1.366**	1.155	0.943
Paper - Unbleached Paperboard, coated	**1.284**	1.085	0.886
Paper - Incada	**0.366**	0.329	0.293
Paper - Invercote	**0.220**	0.206	0.192
Paper - Stora Enso	**0.324**	0.302	0.280
Plastic - PE	**2.094**	1.947	1.800
Plastic - PET	**3.186**	2.708	2.230
Plastic - Bioresin HDPE	**0.195**	0.172	0.149
Plastic - SAN*	**3.460**	3.460*	3.460*
Plastic - ABS*	**3.600**	3.600*	3.600*
Plastic - High Impact PS*	**3.240**	3.240*	3.240*

Greenhouse gas (GHG) outputs are becoming increasingly important.

A higher use of recycled materials leads to a reduction in GHGs.

Opportunity to lower carbon footprint based on paper material choices

*No recycled content deductions due to a lack of availability

www.loraxcompliance.com | info@loraxcompliance.com | www.enviro-pac.com

Case studies

Merck KGaA

- Developed a four-year approach to drive improvement within a complex system.

- Targets set for each goal with the vision to continue to new goals & targets beyond 2024

SHRINK – Reduce amount of packaging

- Mergk KGaA collaborates with packaging, distribution and procurement teams to minimize the amount of packaging that we use to pack and ship our products to our customers.

Redesign of cut disc membranes packaging system

The redesign of the packaging led to a **22%** reduction of plastic consumption. It represents **6,7 tons of plastic saved annually**.

It also improved ease of use for customers.

SHRINK – Reduce amount of packaging

Redesign of Lynx S2S packaging

The redesign of the packaging led to a **57%** reduction of the total packaging weight.

For a customer in Belgium, this reduction in packaging weight reduces annual life cycle greenhouse gas emissions by **79,000 kg CO_2e**, which is equivalent to the CO_2 emissions from combustion of **33,500 liters** of gasoline.

SHRINK – Reduce amount of packaging

Bulk Packaging solution for Millistak PODs

This bulk packaging solution was developed in collaboration with a biotech customer.
It allows to reduce the amount of corrugated packaging **by 24%** and the operator time at reception **by 80%** compared to standard individual packaging.

SHRINK – Reduce amount of packaging

Lower distribution packaging-to-product volume ratio

The redefinition of the range of distribution boxes used at the Strasbourg Distribution Center has led to a reduction of **17%** of the air in the boxes during shipment, resulting notably in reduction of consumption of packaging materials and packaging waste at customer sites.

Ship less air!

Similar initiatives are currently underway at other distributions centers, and we're also investigating other technologies, such as "box-on-demand."

SECURE – Achieve zero deforestation

- We focus on demonstrating responsible sourcing and increasing certified and recycled content of our wood and fiber-based packaging materials.

2019 Deforestation Survey Results

To move toward our zero deforestation target, we conducted our first deforestation survey in 2019.
The results show that **66% by mass** of our wood and fiber-based packaging materials used in our manufacturing plants are aligned with our zero deforestation.

SWITCH – Improve plastic sustainability

- We collaborate with packaging, distribution and procurement teams to select materials and packaging techniques that are more sustainable.

Tackling Polystyrene Usage

We previously used Expanded Polystyrene (EPS) for packing glass reagent bottles for shipment.

We have replaced EPS by molded pulp packaging material for some of our packaging configurations. Today this represents **3,000,000** inserts annually. This leads to a reduction of CO_2 emissions and customers' packaging waste.

SAVE – Maximize recycling

- We focus on developing packaging solutions that can be easily recycled or even reused through specific programs.

Returnable Containers

Our solvents can be delivered to our customers in special **reusable** steel containers.

Our customers can return empty stainless-steel containers to us for refilling, enabling us to significantly reduce the consumption of primary packaging materials.

More than 50,000 containers are in circulation in Europe and in the U.S.

Case Studies: Right-sizing

- FSC Certified
- ½ Box size
- Waste reduced by 90%
- NeO is an innovative technology which replaces traditional freeze-dried vaccine pellets in glass vials with innovative effervescent tablets of vaccine in blister packs.
- Each tablet contains a freeze-dried vaccine virus, packaged in a light-weight aluminum blister. Active vaccine ingredients are the same as the ones used for viral vaccines in glass vials.

Case Studies: Eliminate Layer / Films

Simplifying to a one-piece design (Abilify)

- Annual **cost savings** of more than $2 million
- 70 tons **less paper** per year
- 30% more product per pallet, leading to 30% **less containers shipped** (finished product) and less energy required for shipping

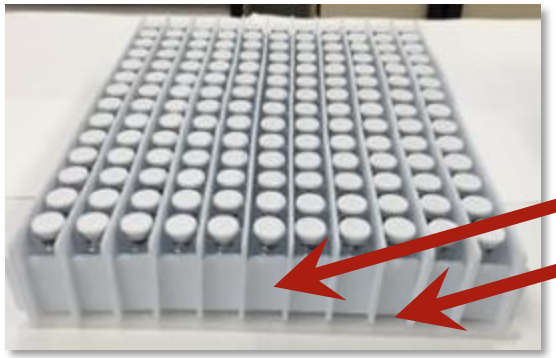
Greener Packaging Materials

Drug Product Bulk Nesting Unit Package (BNU)

Blue Polyurethane Foam

Made With Ozone Depleting Chemicals

Difficult to Recycle & Dispose



NEW Drug Product Bulk Nesting Unit Package

Recyclable Polypropylene Partition

Recyclable Polyethylene Foam Pad

Case Studies: Reduced Environmental Footprint

- **Flame Treatment Elimination**: Pressure sensitive and shrink labels do not require the use of flaming to adhere to HDPE and PP bottles. This makes the flaming process unnecessary. For every 5 million bottles not flamed approximately 3 metric tons of CO2 is eliminated. Flaming calculation tool available upon request to determine reduction in carbon footprint. Opt out and conserve natural gas. Easy way to reduce the carbon footprint since most labels do not require this process.
- **100% PCR**: Resin derived from 100% recyclable post-consumer material
- HDPE Bioresin: Plastic bottles made from ethanol derived from renewable resources (e.g. sugarcane)
  - *In general, for every 1 ton of bioresin used, approximately 3.1 tons of carbon dioxide are captured from the atmosphere on a cradle-to-gate basis.*

Replacing plastic kits by solid board packaging

- The task
  - Replace plastics
  - Postal delivery
  - Continuous use
- Solution
  - Easy to use solid board case with inserts: The lid can be closed on the front side thanks to two flaps which enter the box on the inside.
- Results
  - Eco-friendly solution
  - Easy to use for operator and patient
  - Holds content in place and tidy
  - Folded or mounted

New packaging

Solid board packaging for sensors

- The task
  - Replace existing styrofoam/plastic packaging with a single material
- Solution
  - Single-material easy-to-set up solution without additional inlays
- Results
  - Monomaterialsolution -easyto recycle
  - Easy to set up -higher efficiency
  - Lower cost and lower complexity
  - Winner -World Star and Swiss Star Packaging Awards 2016

Corrugated packaging for eco-friendly cleaning capsules

- The task
  - Replace existing blister packaging to fit product philosophy
  - Child safe
- Solution
  - Corrugated single retail pack for transport and shelf-ready packaging
- Results
  - Child-proof with two-stage opening mechanism
  - Tamper evident but non-destructive seal
  - Avoids unnecessary waste
  - Reduced carbon footprint

Corrugated single retail pack for transport and shelf-ready packaging

- corrugated pack including inserts to secure the product in place

OCEAN SAVER

DS Smith

BREAK 1

Conference resumes at 15:05. Please come back in 10 minutes.

If your question could not be addressed, please feel free to email it to info@pscinitiative.org and the relevant speaker will provide an answer in writing.

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Draft Indian Standard: Current Status and Ramifications on PiE/AMR

SHIVANANDA SHETTY
PARTNER, ERM

MUGUNDAN RAMACHANDRAN
SENIOR CONSULTANT, ERM

AGENDA

1. Brief Introduction to the Proposed Environmental Standards for Bulk Drug and Formulation Industry

2. Key Challenges and Ramifications for the Indian Industry

3. Voice of Indian Pharma Companies – Outcome of ERM's Online Survey, August 2020

4. Summary of Amendments and Modifications in the Draft Standard Proposed by the Expert Committee of MoEF&CC

Speaker Bio

Shivananda Shetty, Partner, ERM India Private Limited

- Shiva is Partner with ERM India, he is a graduate in Chemistry from Mumbai University, Post Graduate in Policy and Regulatory Studies from TERI and PhD from Delhi University. He has more than 25 years of experience in Environmental Health, Safety and Sustainability sector across various sectors including Pharmaceuticals. He started his career as a chemist at SGS India and has worked for more than 5 years in the Pharmaceutical services wherein he was involved in QA/QC studies of the pharmaceutical products as per the Indian, British, Europe and Japanese Pharmacopeia using chemical, instrumental (GC-MS, HPLC, FTIR) and microbiology techniques. He was the Director of the Laboratory Business at SGS India which included the pharma testing facility that had approvals from NABL, Indian GLP and USFDA for QA/QC of the Indian pharmaceutical products. He has been led the studies for various clients to assess the trace level of the pharma products in environment at various water bodies across India. His team was also involved in studying the impact of oregano grass on the MRSA (a well-known antibiotic-resistant bacterium) along for University of West England. SGS was awarded the prestigious 2008 SEED award for the work He was involved in developing the capability and getting ISO 17025 accreditation for testing antibiotics in seafood and other food products like Milk, Honey using modern techniques like HPLC, LC MS MS, GC MS etc.

- He leads the Sustainability and Climate Change Services at ERM India and has worked closely with Pharma companies in India which includes consulting for Sustainability reporting, Dow Jones Sustainability Index (DJSI) disclosure, Carbon disclosure program (CDP). He is also the partner in charge for various PSCI audits for companies like Pfizer, Novartis, GSK covering their major suppliers in India. He and his team are involved in supporting the companies in India for implementing the AMR Alliance guidelines across their own operations and the supply chain in India. He has also been involved as expert in Environment Due Diligence for healthcare, clinical research and pathological labs in India.

Speaker Bio

Mugundan Ramachandran, Senior Consultant, ERM India Private Limited

- Mugundan is a Senior Consultant currently working with ERM based in Bangalore, India. He has a Master's Engineering Degree in Environmental Science & Technology and a Bachelor's Degree in Biotechnology from Anna University, Chennai. He has over ten (10) years of consulting experience in the field of Environmental Engineering and Water Resource Management. Mugundan has a rich experience in undertaking Water audits, Wastewater Management studies, EHS Compliance audits, Regulatory review and Environmental Due Diligence (EDD) audits across a variety of industrial sectors. He is an expert in water balancing, process water optimization, wastewater treatment, due diligence, site assessments and regulatory compliance. His experience also includes design, adequacy assessment and commissioning of wastewater and sewage treatment plants. He has undertaken more than 200 environmental consulting assignments till date in diverse manufacturing sectors such as textiles/apparel, pharmaceutical, oil & gas, chemicals and paper. He is a Quality Council of India (QCI) certified '*Functional Area Expert'* in the field of Water Pollution, Prevention and Control. Mugundan has been closely working with some of the pharmaceutical companies in evaluating their overall AMR risks from the manufacturing facilities in line with guidelines of AMR Industry Alliance.
- Since 2016, Mugundan has been working with a number of pharmaceutical companies and other agencies on evaluating PiE/AMR impacts from antibiotic manufacturing. He is well-versed with the requirements of Common Antibiotic Manufacturing Framework (CAMF) by AMR Industry Alliance and has undertaken a number of assessments in this regard. He also played a vital role in the development of an in-house online tool to assess the compliance of manufacturing facilities against the requirements of CAMF.

Proposed Environmental Standards

- MoEF&CC published a draft notification on the proposed environmental standards for Bulk Drug and Formulation (Pharmaceutical) Industry on 23rd January 2020.
- The notification sets up effluent discharge standards at the final outlet of ETP - for various physico-chemical parameters, solvents, *API's and standards for 121 antibiotic residues*.
- In addition, the notification also includes emission standards for process reactor vents/tank farm vents and total solvent losses (<3% of the solvent used).
- No distinct exemption provided for ZLD industries in the draft notification.

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

NOTIFICATION

New Delhi, the 23rd January, 2020

G.S.R. 44(E).— The following draft of the notification, which the Central Government proposes to issue in exercise of the powers conferred by sections 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) is hereby published, as required under sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, for the information of the public likely to be affected thereby; and notice is hereby given that the said draft notification shall be taken into consideration on or after the expiry of a period of sixty days from the date on which copies of the Gazette containing this notification are made available to the public.

Any person interested in making any objections or suggestions on the proposals contained in the draft notification may forward the same in writing, for consideration of the Central Government within the period specified above to the Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi-110003, or send it to Member Secretary, CPCB and Scientist 'E' Ministry at the e-mail address i.e. mscb.cpcb@nic.in and h.kharkwal@nic.in.

Draft Notification

The Central Government hereby makes the following rules further to amend the Environment (Protection) Rules, 1986, namely:-

1. **Short title and commencement**- (1) These rules may be called the Environment (Protection) Amendment Rules, 2019.

   (2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Environment (Protection) Rules, 1986, in Schedule-I, for serial number 73 and the entries relating thereto, the following serial number and entries shall be substituted, namely:-

Sl. No.	Industry	Parameters	Standard
1	2	3	4
"73	Bulk Drug and Formulation (Pharmaceutical)	**A. EFFLUENT STANDARDS**	
			For final outlet of ETP Limiting value for concentration (in mg/l except for pH and Bio assay)
		i) Compulsory Parameters	
		pH	6.0 -8.5

Salient Aspects of the Standard

- Proposed concentration of API's at the final outlet of ETP shall be 0.05mg/L.
- Proposed concentration for 121 antibiotic residues is lesser than the PNEC values established by AMR Industry Alliance.
- Reuse of treated effluent for gardening/horticulture shall not be considered as ZLD in Bulk drug and Formulation industries.
- The notification also mandates incineration of sludge containing antibiotics.
- Since its release, various industries and industrial bodies have raised numerous concerns and objections on the draft notification*.

* http://www.pharmabiz.com/NewsDetails.aspx?aid=121659&sid=1

D. Antibiotic Residues in the treated effluent of Bulk Drug and Formulation Industry and CETP with membership of *Bulk Drug and formulation* Units

Individual antibiotic residues will be equal to or less than the values given in the below table.

Parameter		Limiting value for concentration (µg/l)
i.	Amikacin	6.40
ii.	Amoxicillin	0.10
iii.	Amphotericin B	0.01
iv.	Ampicillin	0.10
v.	Anidulafungin	0.01
vi.	Avilamycin	3.20
vii.	Azithromycin	0.01
viii.	Aztreonam	0.20
ix.	Bacitracin	3.20
x.	Bedaquiline	0.03
xi.	Benzylpenicillin	0.10
xii.	Capreomycin	0.80
xiii.	Cefaclor	0.20
xiv.	Cefadroxil	0.80
xv.	Cefalonium	8.40
xvi.	Cefaloridine	1.60
xvii.	Cefalothin	0.80
xviii.	Cefazolin	0.40
xix.	Cefdinir	0.10
xx.	Cefepime	0.20
xxi.	Cefixime	0.02
xxii.	Cefoperazone	0.20
xxiii.	Cefotaxime	0.04
xxiv.	Cefoxitin	3.20
xxv.	Cefpirome	0.02
xxvi.	Cefpodoxime	0.10
xxvii.	Cefquinome	0.64
xxviii.	Ceftaroline	0.02
xxix.	Ceftazidime	0.20
xxx.	Ceftibuten	0.10
xxxi.	Ceftiofur	0.02
xxxii.	Ceftobiprole	0.09
xxxiii.	Ceftolozane	0.76
xxxiv.	Ceftriaxone	0.01

Key Challenges and Ramification for the Indian Pharma Industry

1. STRINGENT DISCHARGE LIMITS FOR API'S & ANTIBIOTIC RESIDUES

- Proposed Antibiotic discharge concentrations are much lesser than the PNEC values.
- India is the first country to prescribe antibiotic discharge standards.*

2. NON-DISTINCTION BETWEEN ZLD AND NON-ZLD UNITS

- No clear distinction between ZLD and non-ZLD units in the draft notification.
- Reuse of treated effluent for gardening/horticulture shall not be considered as ZLD.

3. ANALYSIS OF API'S & ANTIBIOTIC RESIDUES

- Uncertainty on the test methods and standards for all API's and antibiotics in complex wastewater streams.
- Laboratory infrastructure in India.

4. IMPLICATION ON OPERATING CAPITAL

- Higher operating cost associated with technological upgradation of wastewater treatment plants in order to comply with the discharge standard.
- Additional cost expenditure with respect to laboratory analysis of effluents and handling & disposal of sludge containing antibiotics.

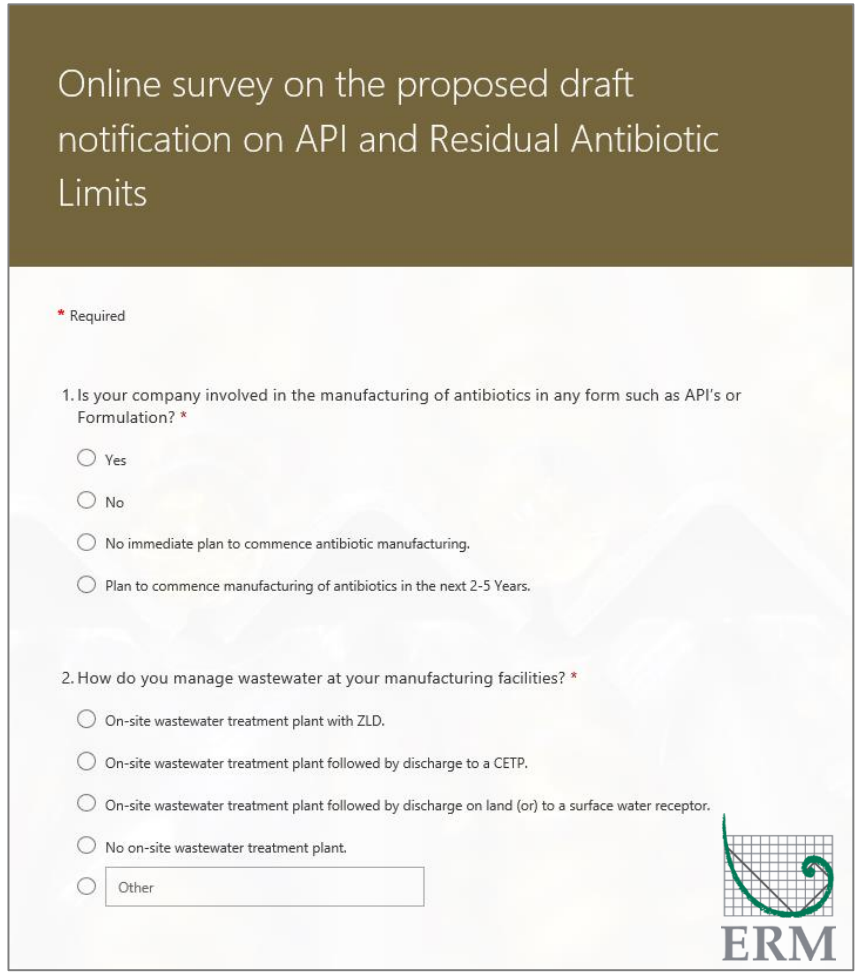
5. PERSECUTIONS, REPUTATIONAL & BUSINESS RISKS

- Litigations, regulatory risks and penalties associated with the non-compliance to the proposed discharge standards.
- Apprehension of Industry becoming economically constraint and non-competitive in the International market.

*https://www.europeanpharmaceuticalreview.com/article/115074/limiting-antibiotic-manufacturing-discharge-in-indian-wastewater/

Outcome of ERM's Online Survey

- Online Survey to gather views and perception of Indian Pharmaceutical Companies on the draft notification.
- 11 questions focussing on the interpretation and challenges for the industry.
- More than forty (40) companies invited for the survey.
- Survey duration of four weeks – 1st to 31st August 2020.
- 75% of the respondents are into antibiotic manufacturing.
- 66% of the respondents mentioned to have an on-site wastewater treatment plant followed by Zero Liquid Discharge (ZLD).



Outcome of ERM's Online Survey

Q.1) Based on your view, can you please identify and rate the key challenges (on a scale of 1 to 5, with 1 being the highest priority) associated with the implementation of this draft standard?

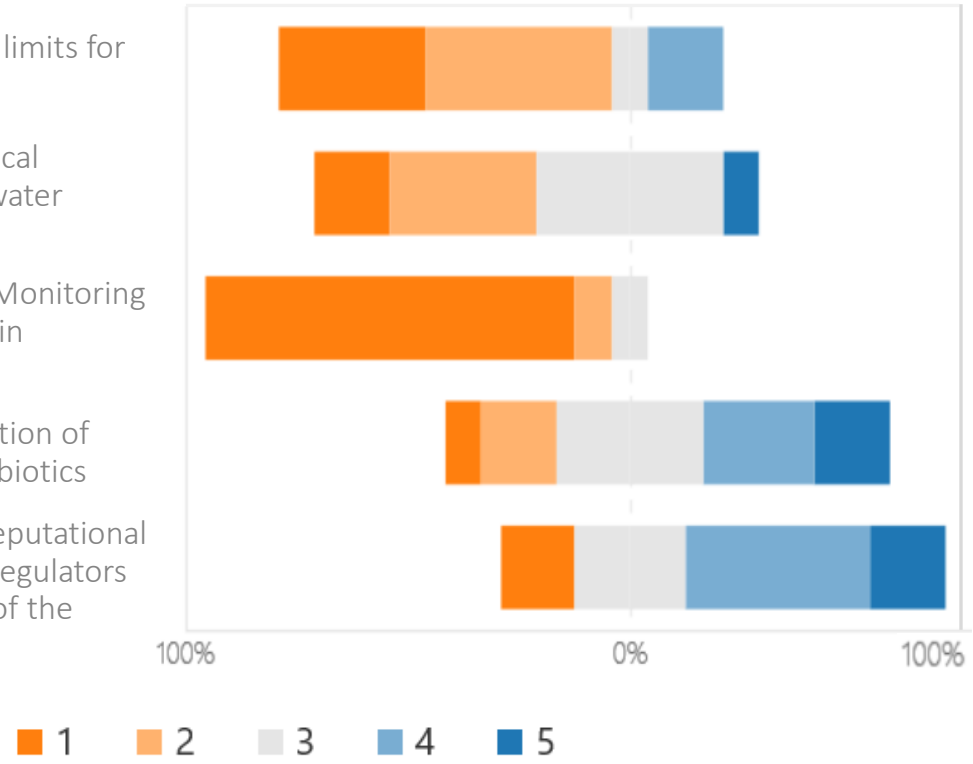
1. Stringent discharge limits for Antibiotics and API's

2. Need for technological upgradation in wastewater treatment plants

3. Measurement and Monitoring of Antibiotics and API in wastewater

4. Mandatory incineration of sludge containing antibiotics

5. Persecutions and Reputational risks posed by NGOs/regulators post implementation of the standard



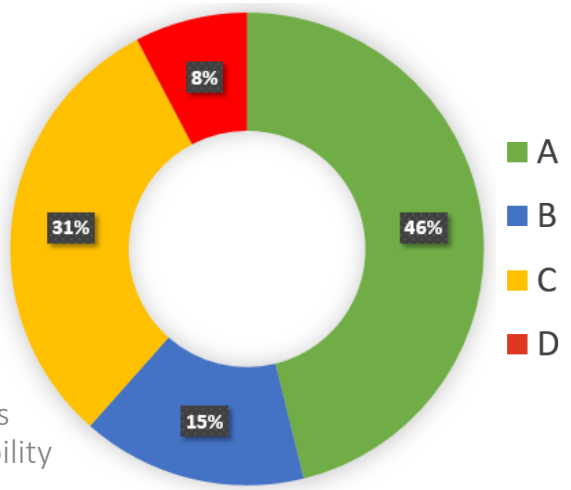
Q.2) The proposed standard does not provide a clear distinction between ZLD and Non-ZLD units. What is your perspective on this aspect?

A. ZLD units should be completely excluded from the scope of this standard as there is no discharge of treated/untreated effluents from the site premises.

B. While the standard should exclude ZLD units, there is a need for additional infrastructure/controls to be implemented while managing the antibiotic/API containing wastewater in ZLD Units;

C. ZLD units should also come in ambit of this standard as there is an uncertainty on the ability of existing wastewater treatment systems to completely remove (or) inactivate the antibiotics/APIs present in pharmaceutical effluents;

D. None of the above



Outcome of ERM's Online Survey

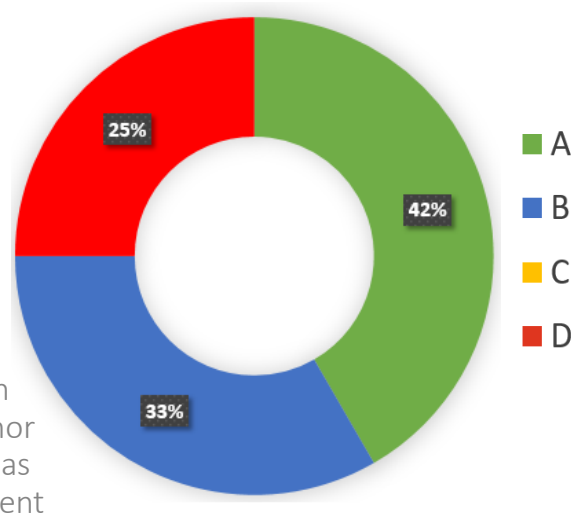
Q.3) What is your opinion on the need for technological upgradation in the wastewater treatment plants in order to meet the proposed discharge standards for API's and Antibiotic Residues?

A. Uncertain. Currently, there is no strong scientific evidence to substantiate the antibiotic removal efficiencies of various conventional and advanced wastewater treatment technologies.

B. The existing wastewater treatment plants need major upgradation and revamp in order to comply with the proposed discharge standards for API's and Antibiotics; Significant CAPEX needs to be earmarked for this purpose;

C. No major upgradation would be required in the wastewater treatment plants. Certain minor operational intervention in the process (such as source control and segregation) will be sufficient to comply with the proposed discharge standards for API's and Antibiotics;

D. None of the above



Q.4) Draft standard mandates incineration of sludge containing antibiotic residues. What is your perspective on this?

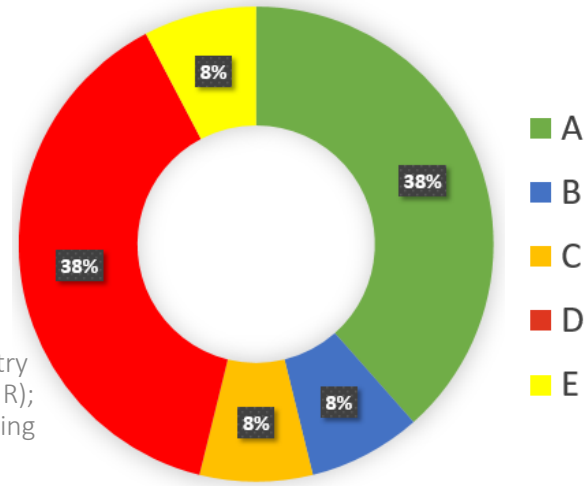
A. Mandatory incineration would mean significant increase in operational cost. This will lead to the Indian pharmaceutical industry becoming economically constraint and non-competitive with international markets; Companies should be allowed to dispose such sludge in approved TSDF facilities or for co-incineration.

B. While the requirement of mandatory incineration should be reconsidered by MoEF&CC, there is a need for additional controls to be implemented by pharmaceutical companies for ensuring deactivation and destabilization of active antibiotics in such sludge before disposal;

C. This is a welcome decision by MoEF&CC as sludge containing active antibiotics from Pharmaceutical industry poses a high risk towards Anti-Microbial Resistance (AMR); this standard should be mandated for all sludge containing residual antibiotics;

D. MoEF&CC should also take into account the availability of common hazardous waste incinerators across different pharmaceutical clusters and states in India before implementing this standard.

E. None of the above



Outcome of ERM's Online Survey

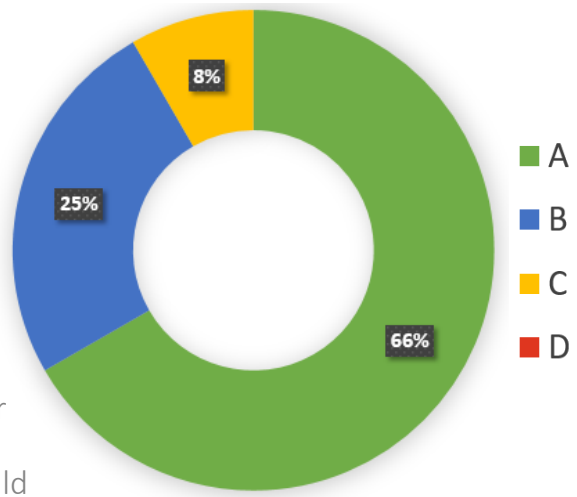
Q.5) As per the draft standard, the API's and Antibiotic residues are required to be analysed regularly in the treated effluent? What is your perspective on the analytical tools such as test methods and standards for such analysis?

A. Validated test methods, standards and laboratory infrastructure may not be available for all API's and Antibiotics manufactured in India;

B. While the standard methods are either already available (or) can be developed with the help of scientific community, conducting such tests on a regular basis is not-viable considering the financial implications and the management time involved;

C. Validated test methods, standards and laboratory infrastructure are readily available for all API's and Antibiotics manufactured in India; the regular analysis of API's and Antibiotics should be mandated for all pharmaceutical units irrespective of the status of implementation of ZLD.

D. None of the above



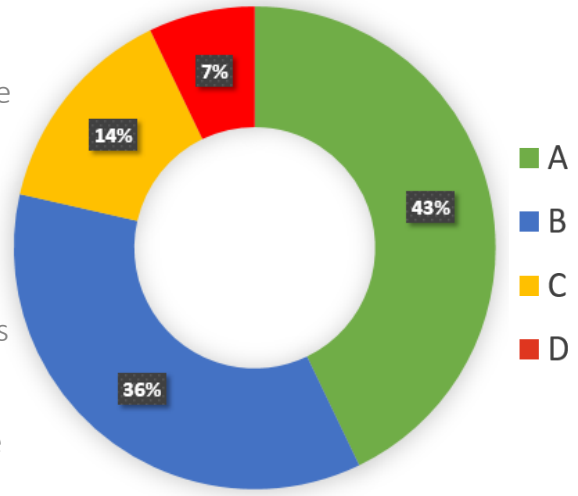
Q.6) In your view, what are the key changes / modifications that needs to be considered by MoEF&CC in the draft standard?

A. MoEF&CC should revisit certain aspects of the standard (such as PNEC values, sludge incineration etc.) and revise the same in accordance with inputs and consultation with a larger group of stakeholders from the industry and scientific community before prescribing the final discharge standard;

B. The standard should be made applicable for non-ZLD units only as ZLD units don't discharge any wastewater outside the site premises.

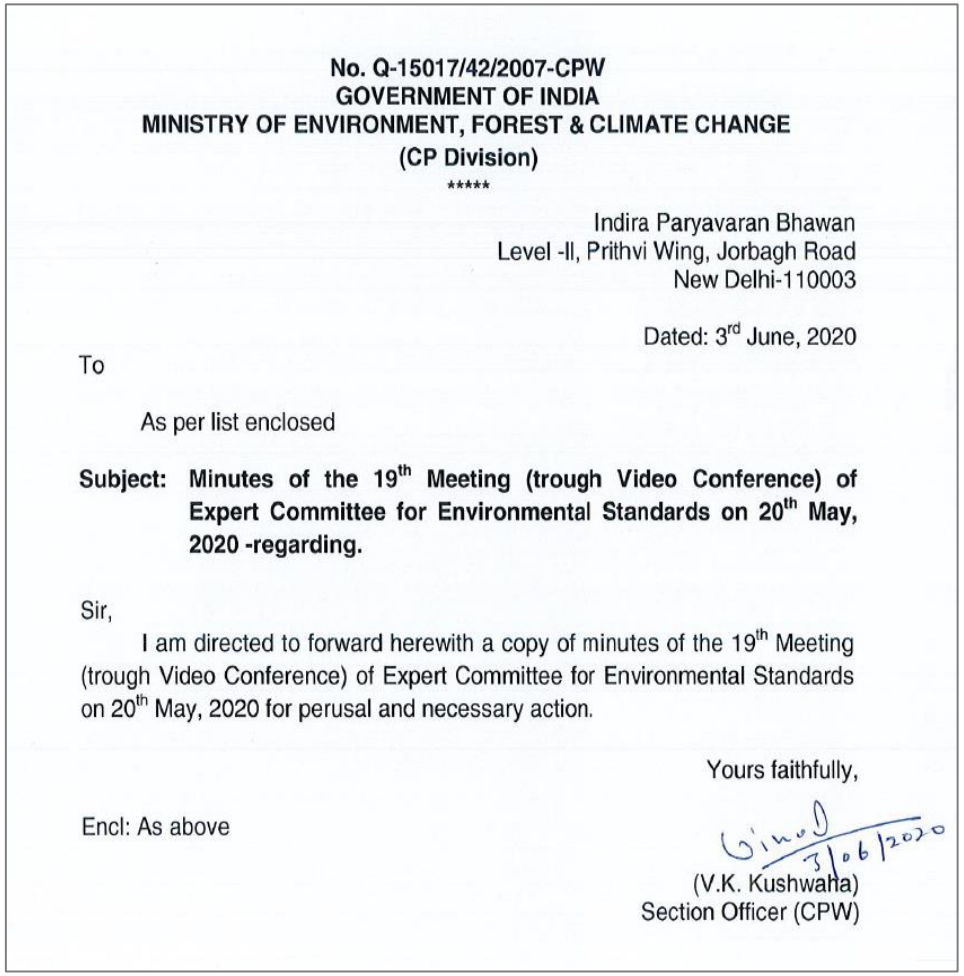
C. With a long term vision of curbing AMR and its impacts in the country, the standard should be rolled out in its complete form without any modification; however MoEF&CC should provide sufficient time for the industries to implement operational and technological changes required in order to comply with various requirements of the standard;

D. None of the above



Amendments and Modifications Recommended by the Expert Appraisal Committee

- The draft notification was considered for finalization in the 19th Meeting of Expert Committee for Environmental Standards on 20th May 2020.
- More than 35 suggestions received from industry associations, individual experts and industries were deliberated for their relevance and feasibility.
- Joint Secretary, Ministry of Chemicals and Fertilisers, Department of Pharmaceuticals stressed on the following aspects:
  - Proposed norms shouldn't result in excess financial burden to the Industry
  - Standard on AMR may be a challenge for the industry to meet
  - The committee may consider appropriate concerns raised by the industry



No. Q-15017/42/2007-CPW
GOVERNMENT OF INDIA
MINISTRY OF ENVIRONMENT, FOREST & CLIMATE CHANGE
(CP Division)
*****

Indira Paryavaran Bhawan
Level -II, Prithvi Wing, Jorbagh Road
New Delhi-110003

Dated: 3rd June, 2020

To

As per list enclosed

Subject: Minutes of the 19th Meeting (trough Video Conference) of Expert Committee for Environmental Standards on 20th May, 2020 -regarding.

Sir,

I am directed to forward herewith a copy of minutes of the 19th Meeting (trough Video Conference) of Expert Committee for Environmental Standards on 20th May, 2020 for perusal and necessary action.

Yours faithfully,

Encl: As above

3/06/2020

(V.K. Kushwaha)
Section Officer (CPW)

Amendments and Modifications Recommended by the Expert Appraisal Committee

01 Applicability (ZLD/Non-ZLD)

The notification will be applicable for **any discharge of treated process water** to inland water bodies or for horticulture or irrigation or land disposal from any industry and or CETP.

02 API Discharge Norms

Total API discharge norms **shall be removed** owing to the complexity and non-availability of standardised test methods.

03 Antibiotic Discharge Standards

PNEC values shall be applicable at the outlet/discharge point for both CETP as well as industry (other than member industries of CETP).

04 Industries Discharging to CETP's

Member industries discharging to CETP's will be governed by the **provision of CETP norms** dated 01.01.2016*.

05 CETP's

CETP's receiving effluent from any bulk drug and formulation manufacturing shall be **subjected to AMR parameters** (antibiotic standards).

06 Sludge Management

Antibiotic containing sludge can be handled in **accordance with** the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016.

- *CPCB to issue guidelines and requisite protocol on sampling and analysis for AMR tests within 12 months.*
- *AMR parameters shall be applicable after expiry of one year from the date of this notification.*

* https://parivesh.nic.in/writereaddata/ENV/envstandard/envstandard2.pdf

Summary of Exemptions/Applicability of the Draft Notification*

Nature of Bulk Drug & Formulation Industry / CETP	Applicability of the Draft Notification* #
Zero Liquid Discharge along with complete reuse/recycle of treated process wastewater in utility/process applications (no discharge on land)	No
On-site wastewater treatment followed by discharge of treated process wastewater to inland water bodies or for horticulture or irrigation or land disposal	Yes
Member industries disposing wastewater to CETP's	No
Non-member industries disposing wastewater to CETP's	Yes
CETP's receiving effluents from bulk drugs and formulation units (for the applicability of AMR parameters)	Yes

**Subject to the recommendations of expert committee being accepted by MoEF&CC.*
 # Some aspects of the notification are applicable to all/certain types of industry irrespective of how the wastewater is handled. Please refer the minutes of expert committee meeting for detailed information.

Analysis of API's and Antibiotics

- Requires specialised high end equipment's like LC-MS/MS-MS, GC-MS/ MS-MS, with additional accessories like purge and trap options.
- Sample preservation and transportation.
- Not much officially published methodology for API/ Antibiotics; VOC and SVOC methodology already available as per USEPA.
- Validation of the extraction and detection process; first time validation requires system suitability, Specificity, Linearity, Precision, Accuracy, LOD, LOQ & Robustness. Normally it takes couple of months for validation.
- The Reference Standards are very expensive. 20,000- 100,000/- per standard.
- Several Indian commercial laboratories (> 15 numbers) are funded by the government and have the capability for testing API and antibiotic residue across India – Hyderabad, Chennai, Delhi-NCR, Kolkata, Cochin, Mumbai. These laboratories are regularly testing food products- Seafood, Milk products for export to Europe and US for antibiotic
- Multi-residue analytical methodology can be developed in collaboration with leading Indian commercial laboratories and regular proficiency testing methodology through a project.

D. None of the above

To ask questions, please go to https://app.sli.do/ and enter the event code: #PSCIIndia

BREAK 2

Conference resumes at 16:05. Please come back in 10 minutes.

If your question could not be addressed, please feel free to email it to info@pscinitiative.org and the relevant speaker will provide an answer in writing.

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

Introduction to sampling and analysis of APIs in wastewater

JONATHAN STANWAY

BIOTECHNOLOGY & ENVIRONMENTAL DOWNSTREAM MANAGER

GLAXOSMITHKLINE

Speaker Bio

Jon Stanway

BEng (Chemical Engineering) MSc (Biochemical Engineering)

CEng Chartered Engineer of the Institute of Chemical Engineering (IChemE)

14 years at GSK across API development and manufacture.

BIOTECHNOLOGY & ENVIRONMENTAL DOWNSTREAM MANAGER, GSK

- Pharmaceuticals in the Environment expert
  - Manufacturing controls and wastewater treatment
  - AMR Industry Alliance Manufacturing Roadmap risk assessment & compliance
  - Mass Balance calculation and analytical characterisation.
- Small molecule biotechnology industrialization.

Introduction to sampling and analysis of APIs in wastewater

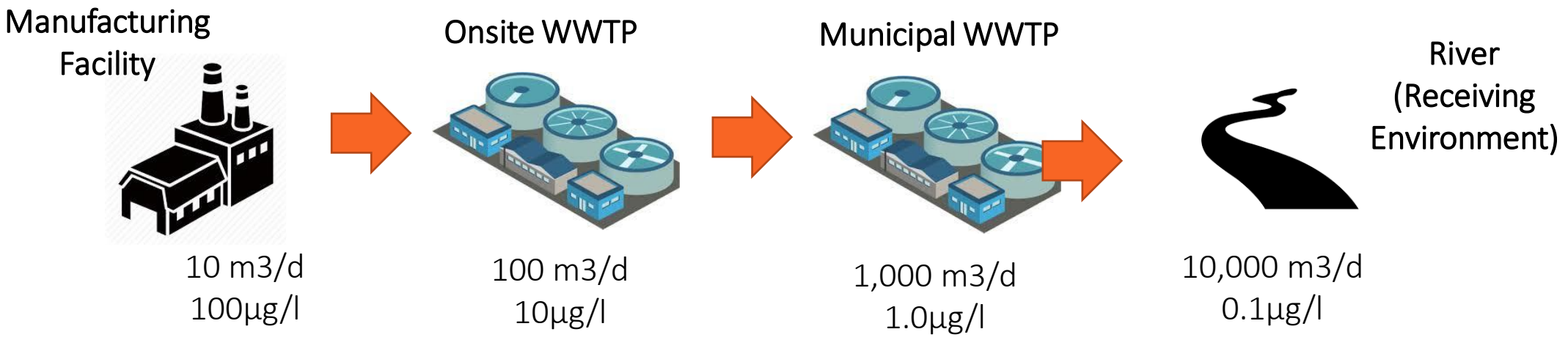
- Why Sample?
- Where to Sample?
- When to Sample?
- How to Sample?
- How to Analyse?

Why Sample Wastewater?

- Assessment of compliance to regulatory or industry discharge limits can be done by mass balance calculation accounting for **worst-case** assumptions for the following;
  - **Losses of API** to wastewater from manufacturing operations e.g. from process waste and cleaning streams.
  - **Removal efficiency** in wastewater pre-treatment and treatment operations.
  - Onsite and offsite **dilution** e.g. accounting for dilution in downstream municipal wastewater treatment and in the location of environmental discharge.
- Refinement with analytical data may be required in some circumstances;
  1. Where the mass balance calculation indicates discharge above or close to the limit.
  2. Where there is limited data to establish worst-case assumptions.
  3. To characterise actual API removal efficiency in wastewater treatment.
  4. For purposes of routine monitoring of performance.

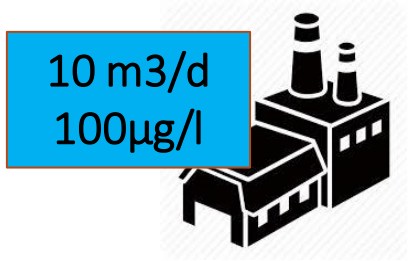
Where to Sample?

- Location of wastewater sampling dependent on several key factors;
  1. Primary rationale for sampling – what's the most important information required?
  2. Constraints of analytical methods.
  3. Access to sampling locations.
  4. Likelihood of noise or interference from other factors.
- Example: **Site wants to determine compliance to a PNEC limit of 0.10µg/l.**

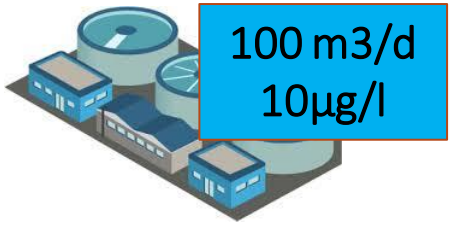


Where to Sample?

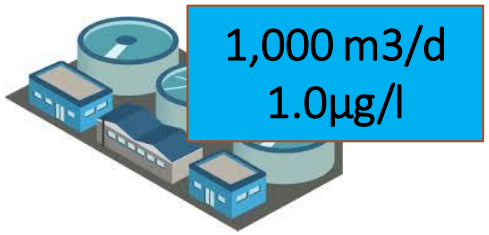
Manufacturing Facility



Onsite WWTP



Municipal WWTP



River (Receiving Environment)

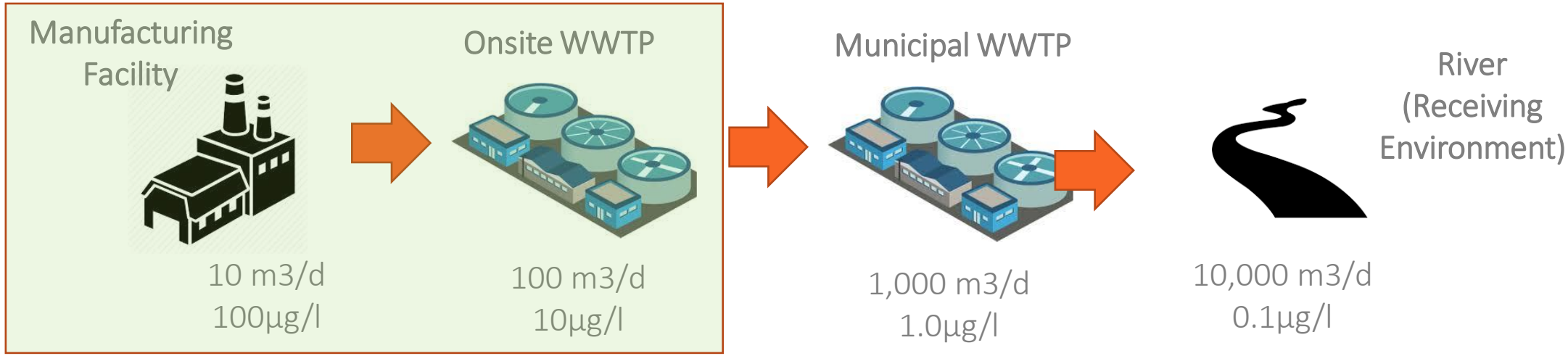
Easy Access for Sampling → Difficult to Access for Sampling

Analysis by HPLC → Analysis by LCMSMS → Difficult to Analyse

No Offsite Noise → Liable to Noise/Interference from Offsite (e.g. other industry, domestic/hospital use)

Doesn't account for removal in WWTP → Removal in WWTP accounted for

Where to Sample?



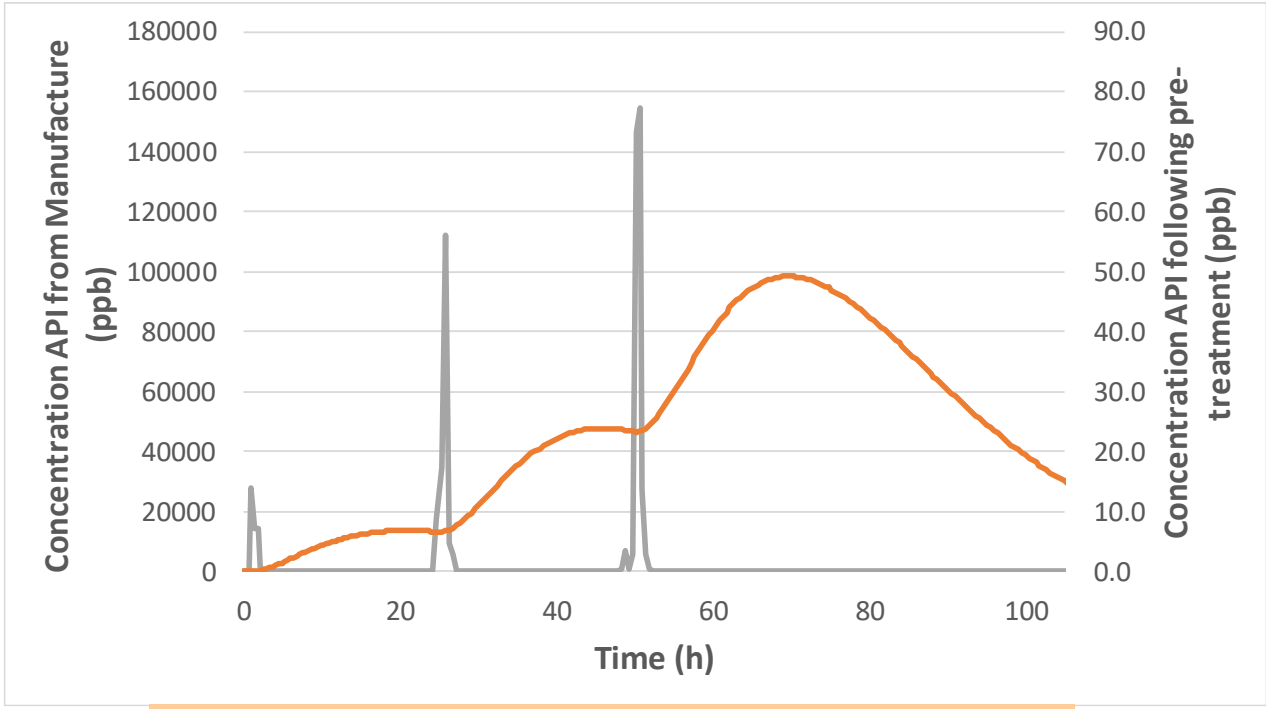
- Optimal sampling programme likely to encompass more than one sample location.
- E.g. sampling of WWTP influent and effluent provides confirmation of concentration discharged from both the manufacturing operation and the site and allows actual API removal efficiency to be determined.
- Other factors such as wastewater pH and presence of biological contaminants (e.g. from WWTP biological treatment) may also impact considerations on location due to sample stability.

What about Zero-Liquid Discharge?

- True ZLD (full recycle) or No offsite discharge?
- Sampling may not be required where treated wastewater is fully recycled e.g. to utilities without any environmental discharge.
  - Sampling of wastewater may still be beneficial to inform antibiotic in the environment risk assessment of e.g. WWTP biosolid.
- For sites discharging treated wastewater for onsite irrigation, understanding API discharge concentration is of particular importance;
  - No dilution/buffering effect from downstream flow.
  - Potential accumulation effects in soil.
- Common approach to apply surface water PNEC limits for soil discharge where soil specific PNEC limits are not available.

When to Sample?

- PNEC concentration limits generally defined for an acute worst-case 24-hour duration.
- Sampling programme design should ensure maximum concentration at the sampling location is measured, accounting for;
    1. **Peak discharge** from manufacturing operations - typically from discrete operations e.g. fermentation harvest, dryer water rinsing.
    2. **Cumulative effects** from overlap in manufacture of an API/DP or multiple formulations containing the same API.
    3. **Residence time** and buffering effects in wastewater collection and treatment.



Delay in peak concentration from manufacturing to WWTP discharge due to residence time in treatment operations.

How to Sample?

- 2 main types of sampling methodology;
  - **Composite sampling:** collected over time through continuous sampling or mixing of discrete samples. Determines average concentration over e.g. a 24 hour period.
  - **Grab sampling:** determines concentration at a specific point of time.
- Use of composite sampling may reduce the number of samples for analysis to assess compliance against a PNEC limit.
- Ensure samples are representative:
  - Taken from centre of the flow channel.
  - Sufficient volume for duplicate analysis.
  - Wearing new gloves for each location.
  - Leakproof containers – and keeping highly contaminated samples segregated from clean samples
  - Using disposable or verified clean equipment for sampling.

Typical composite sample installation

Typical grab sample methodology

How to Analyse?

- Sample transport/storage conditions (time, temperature, exposure to light) should minimise risk of degradation of the API. Ensure couriers can deliver the required conditions.
- Samples with biological contamination e.g. from biological treatment or at high or low pH are liable to degrade APIs resulting in inaccurate results.
- Analysis should be conducted by an accredited laboratory with appropriate technology.
- **Consider risk of signal suppression and limit of detection (LOD).**
- Determine LOD through method development using an equivalent matrix to the wastewater or, ideally, established for each sample through determination of spike recovery.
- Where analysis returns “none detected” or “below the limit of quantification” results, the limit of detection / quantification should be used as a worst-case in mass balance calculations rather than “0”.
- Consider methods utilising sample preparation e.g. US EPA 1694.

LC-MS/MS QTOF for low limit of detection (<ppb) analysis.

To ask questions, please go to https://app.sli.do/ and enter the event code: #PSCIIndia

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

Indian Case Study on Controlling API Releases

JON PEERS

ENVIRONMENTAL DIRECTOR

TEVA API & BIOLOGICS

Speaker Bio

Jon Peers – Environmental Director, Teva api & Biologics

- Located: Madrid, Spain
  - Joined Teva: 2015
  - B.Sc. in Environmental Science;
  - Business Sustainability Management
  - 20+ Years experience in EHS
    - Ciba SC
    - GSK
    - Abbott Laboratories
- Fields of expertise:
  - Safe handling of: powders/solvents/hazardous chemicals
  - Emergency response
  - Waste management
  - Wastewater treatment
  - Air pollution
  - Industrial Hygiene

Serving around 200 million people every day

Our Mission

To be a **global leader** in **generics** and **biopharmaceuticals**, improving the **lives of patients**

Teva's history

1901-1940

A new pharmaceutical industry is founded

1901: Established in Jerusalem by Chaim Salomon, Moshe Levin and Yitschak Elstein

1960-1980

Consolidation of the local pharmaceutical industry

1976: Eli Hurvitz forms Teva Pharmaceutical Industries Ltd.

1980-1990

Global expansion

1984: Hatch-Waxman Act paves way for U.S. generic entry

1990-present

A global leader in generics/ establishes specialty

1996: Teva launches COPAXONE® in the US
2017-2018: Teva launches AJOVY(R) and AUSTEDO (R) in the US

Teva today

A strong specialty medicines portfolio

2019 **revenues**:

$16.9B

40,000

employees

The leading global generic company

68

Manufacturing sites

60

Markets

Over the counter medicines & active pharmaceutical Ingredients (API)

Leveraging scale and enhancing our competitiveness

68
Manufacturing Sites in 33 countries

80B
Tablets / Capsules

20,000
Employees in Operations

3,500
Products

35,000
SKUs

Teva's Sustainability position

- Teva environmental sustainability position includes our approach to reduce API emissions from our manufacturing sites: https://www.tevapharm.com/globalassets/tevapharm-vision-files/teva_environmental_sustainability_position_statement2018.pdf
- Teva EHSMS establishes a global standard for emissions including our approach to reduce API emission from our sites
- AMR is Teva's current priority and by YE2020, we will have completed AMR assessments of 93% of drug products and 100% of drug substances; our AMR position is at: https://www.tevapharm.com/globalassets/tevapharm-vision-files/teva_amr_position_statement2018.pdf

Teva api & biologics by numbers

teva | api

400+
High-quality API products

1,100
Customers

100+
Countries

5,000
Employees

16
Sites worldwide

85
Years

GAJRAULA SITE

Manufacturing

Address
Plot. Nos. A-1, A-1/1 & A-1/2
UPIDC Industrial Area.
Bijnor Road,
Distt.J.P.Nagar
1444235 Gajraula (Uttar Pradesh)
India

Tel 05924252591-92-93
Fax 05924252590
Established 1994 (JK Pharmaceutical)
Acquired by Teva api 2003

MALANPUR SITE

Manufacturing

Address
Plot Nos. Q1 - Q4
Industrial Area, Ghirongi,
District-Bhind, Malanpur
477 117 (Madhya Pradesh)
India

Tel 07539 - 283942
Established 2008

TEVA API INDIA PRIVATE LIMITED

R&D

Address
2-G, 2-H, 2-I Eco Tech – II, Udyog Vihar
Greater Noida
201 306 (Uttar Pradesh)
India

Tel +91-120-4073300
Fax +91-120-4073275

Antibiotic Mass Balance Summary

Common Antibiotic Manufacturing Framework

- Framework includes commitment to quantify antibiotics in effluent by mass balance.

Water Management Program

Principle: Compliance with all applicable regulations. All required environmental permits, licenses, information registrations and restrictions are in place, available for review, and their operational and reporting requirements are followed. Systems are in place for the management of water discharges. Any wastewater or wastewater sludge from on-site wastewater treatment operations with the potential to adversely impact human or environmental health is managed, controlled, and treated prior to release to the environment. Systems are in place to prevent and mitigate accidental spills and releases to the environment.

1) Site possesses a valid authorization/license/permit for water intake (i.e. from groundwater, river or public system) and discharge. Compliance with each condition in the authorization/ license/ permit is demonstrated.
2) Levels of antibiotic in process wastewater are quantified e.g. mass balance.
3) Wastewater sources from operations are characterized and evaluated for treatability and control.
4) Effective wastewater treatment is provided (e.g., neutralization, clarification, settling, inactivation, biological or chemical treatment).
5) Water/wastewater monitoring devices and treatment systems are in good operating condition and appropriately maintained (e.g. in accordance with manufacturer's recommendations).

83% of manufacturing company members have assessed all of their own antibiotics manufacturing sites against the Alliance's new manufacturing **framework**

82% of owned sites **meet the framework's requirements** wholly or in part

56% of products made at member-owned sites are expected to be made in accordance with discharge targets **within the next 3 years** and **88% within the next 7 years**

24% of products made at supplier sites are expected to be made in accordance with discharge targets **within 3 years** and a further **70%** of products made at supplier sites are expected to be made in accordance with these targets **within 4-7 years**.

- It's a Journey…
  - Industry led initiative. Not "compliance" vs "non-compliance"
  - All members at different points of journey but committed to meeting safe discharge targets.

Antibiotic Mass Balance Summary

Common Antibiotic Manufacturing Framework

Background

- AMR Industry Alliance released Common Antibiotic Manufacturing Framework in January 2018.
  - Framework includes commitment to quantify antibiotics in effluent by mass balance.

- AMR Industry Alliance released discharge concentration targets for antibiotics in September 2018 (Predicted No Effect Concentrations - PNECs) and updated January 2020.
  - Target based on lower of PNEC for resistance (PNEC-MIC) or PNEC for ecotoxicity (PNEC-ENV).
  - Target applied at point of entry into environment after mixing.

- PNEC = Concentration of API in environment that is believed (predicted) to not have an impact on the environment demonstrated by testing certain species.

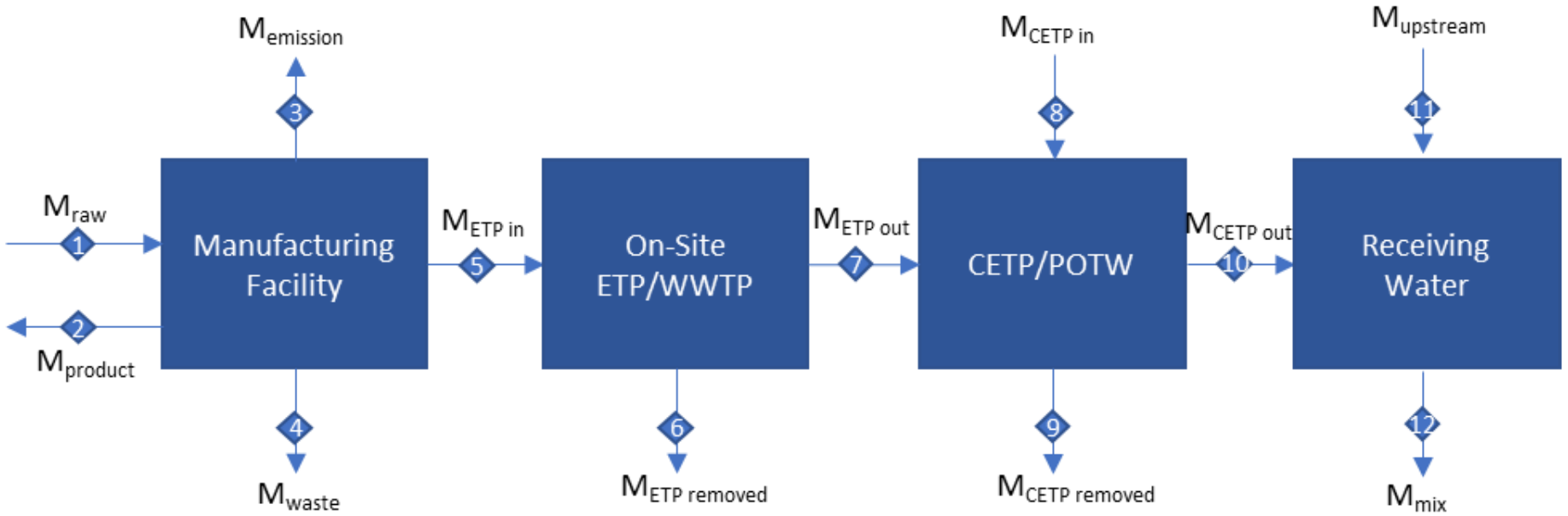
Source for Publication	API	EC_{10} (µg/L)	Species	Test Guideline / Reference	$PNEC_{ENV}$ (µg/L)	$PNEC_{MIC}$ (µg/L)	Lowest Value (µg/L)	$PNEC_{ENV}$ Rationale	Revisions Since Last Version
Bengtsson-Palme & Larsson, 2016	Amikacin				N/A	16.00	16.00	No industry data	No change
Industry Data	Amoxicillin	5.7	*Anabaena flos-aquae*	OECD 201	0.57	0.25	0.25	*Anabaena flos-aquae* $EC_{10} \div 10^{a}$	Industry testing completed
Gonzalez-Pleiter, et al., 2013		6160	*Anabaena sp. CPB4337*	OECD 201					
Industry Data		530000	*Raphidocelis subcapitata*	OECD 201					
Gonzalez-Pleiter, et al., 2013		1500000	*Raphidocelis subcapitata*	OECD 201					
Bengtsson-Palme & Larsson, 2016	Amphotericin B				N/A	0.02	0.02	No industry data	No change
Industry Data	Ampicillin	44.6	*Anabaena cylindrica*	OECD 201	0.60	0.25	0.25	*Cyanobium gracile* $EC_{10} \div 10$	Industry testing completed & new literature data added ($PNEC_{ENV}$ originally 0.87 µg/L)
Le Page et al., 2019		8.3[h]	*Anabaena flos-aquae*	OECD 201					
Industry Data		13	*Anabaena flos-aquae*	OECD 201					
Le Page et al., 2019		18.7	*Anabaena flos-aquae*	OECD 201					
Le Page et al., 2019		5.9	*Cyanobium gracile*	OECD 201					
Industry Data		91500	*Daphnia magna*	OECD 211					
Industry Data		94300	*Desmodesmus subspicatus*	OECD 201					
Le Page et al., 2019		34.3	*Geminocystis herdmanii*	OECD 201					
Industry Data		100000	*Raphidocelis subcapitata*	OECD 201					
Le Page et al., 2019		36.5[h]	*Synechocystis sp.*	OECD 201					
Le Page et al., 2019		38.8[g]	*Synechococcus elongates*	OECD 201					
Le Page et al., 2019		16.2[g]	*Synechococcus leopoliensis*	OECD 201					
Industry Data		19	*Synechococcus leopoliensis*	OECD 201					
Le Page et al., 2019		38[g]	*Synechococcus sp.*	OECD 201					
Bengtsson-Palme & Larsson, 2016	Anidulafungin				N/A	0.02	0.02	No industry data	No change
Industry Data	Avilamycin	1250[b]	*Synechococcus leopoliensis*	OECD 201	125.00	8.00	8.00	*Synechococcus leopolensis* NOEC ÷ 10	Industry data added
Le Page et al., 2019	Azithromycin	5	*Anabaena cylindrica*	OECD 201	0.03	0.25	0.03	*Microcystis aeruginosa* $EC_{10} \div 10$	Original $PNEC_{ENV}$ (0.02 µg/L) based off NOEC, EC_{10} used preferentially
Le Page et al., 2019		10.5[h]	*Anabaena flos-aquae*	OECD 201					
Industry Data		4.4	*Ceriodaphnia dubia*	OECD 201					
Le Page et al., 2019		4.8	*Cyanobium gracile*	OECD 201					
Le Page et al., 2019		3.2	*Geminocystis herdmanii*	OECD 201					
Industry Data		0.33	*Microcystis aeruginosa*	EPA 1002.0					
Industry Data		4600	*Pimephales promelas*	OECD 210					
Industry Data		1.8	*Raphidocelis subcapitata*	OECD 201					

Revision Date: 24 January 2020

Antibiotic Mass Balances

Methodology

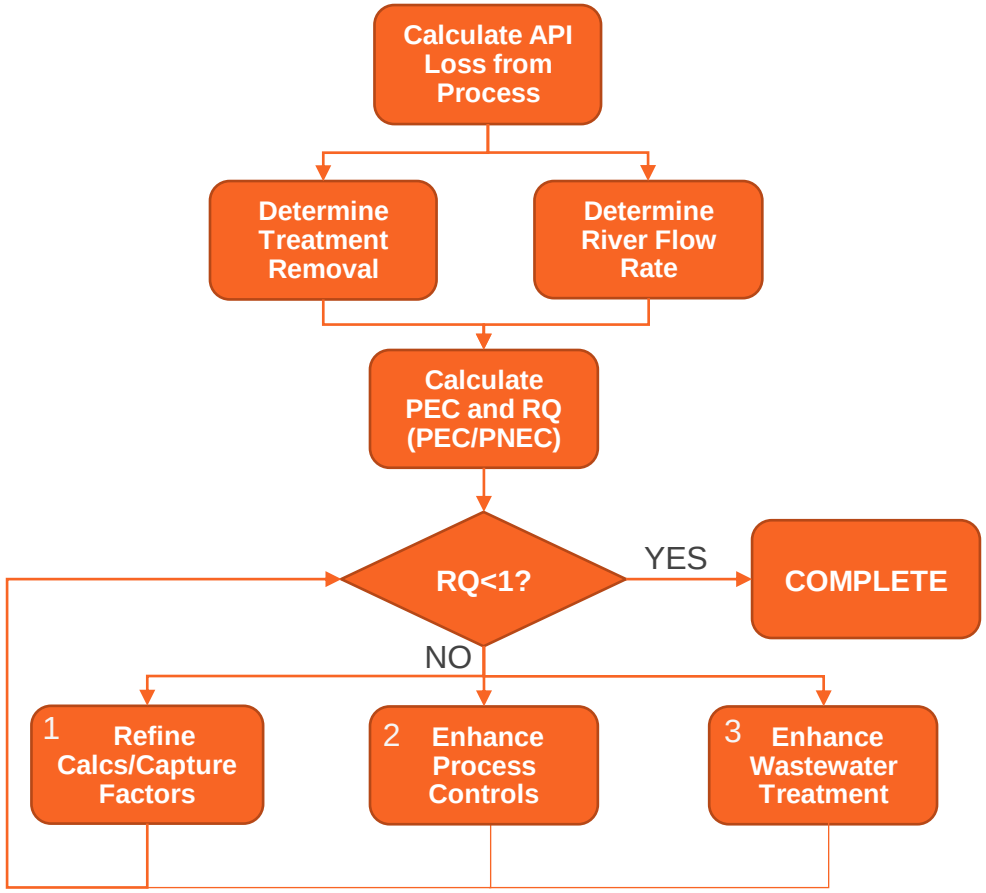
- Methodology outlined by PSCI
- Average daily loss of API from batch based on batch records.
- Removal efficiencies applied for wastewater treatment based on published literature.
- Flow of receiving stream used to calculate antibiotic concentration in environment (Predicted Environmental Concentration - PEC).
- Risk Quotient (RQ) calculated as ratio PEC / PNEC. Target is RQ of 1 or less (i.e. PEC < PNEC).



Antibiotic Mass Balance Summary

Common Antibiotic Manufacturing Framework

- Mass Balance Approach
  - Determine quantity of "unaccounted" API from process
  - Apply "Capture Factors" and assumptions
  - Apply removal efficiencies for wastewater treatment plant(s)
  - Determine mass and concentration in final receiving water
- Impact Assessment
  - RQ<1 (Meets PNEC): No Further Action Required
  - RQ>1 (Does Not Meet PNEC): Additional Assessment/Risk Reduction & Action Plan Required
- Risk Reduction Hierarchy – RQ>1
  - Calculation Refinement: Refine assumptions, conduct additional studies, repeat mass balance/RQ.
  - Process Controls: Implement additional controls, procedures, etc. to reduce quantity of API discharged.
  - Wastewater Treatment: New/enhanced wastewater treatment to reduce quantity of API in effluent.



Teva api & biologics - Malanpur

MALANPUR SITE

Manufacturing

Address
Plot Nos. Q1 - Q4
Industrial Area, Ghirongi,
District-Bhind, Malanpur
477 117 (Madhya
Pradesh)
India

Tel 07539 - 283942

Established 2008

Teva Malanpur manufactures antibiotic products for distribution in the US, Canada and Europe.

The site employs approximately 260 people and creates products from a total of 22 different APIs. Of these APIs, Clarithromycin was selected to be the subject of the PiE assessment, since Clarithromycin is the highest production volume antibiotic at Malanpur.

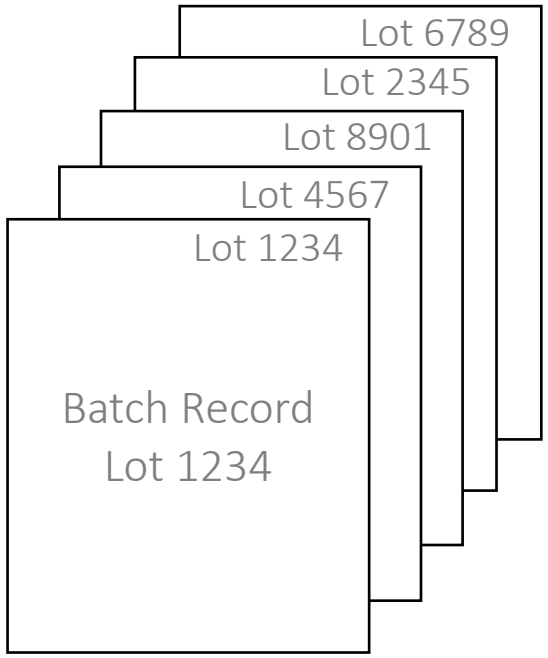
The Malanpur PiE Assessment was performed in July –December 2019 as a part of a Global Teva PiE Assessment initiative. This initiative aims at estimating
the effect of antibiotics emissions to surface water.

The site is a zero liquid discharge facility. Process water is treated in an on site wastewater treatment plant (WWTP), in which both biological and physical-chemical treatment processes are taking place. WWTP effluent is reused as cooling water and for gardening purposes.

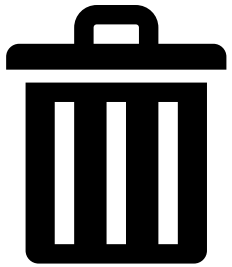
As a result, there is no discharge of WWTP effluent to surface water. Re-use for gardening purposes is currently allowed, but new legislation (currently in draft) might limit or prohibit this in future

Mass Balance Summary

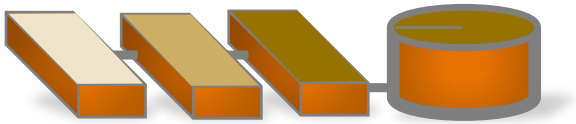
Getting Started: What you need



Completed Batch Records (Mandatory)



Capture Factors (May Be Optional)



Treatment Removal (May Be Optional)

Stream Flow Data (Mandatory)

ZLD

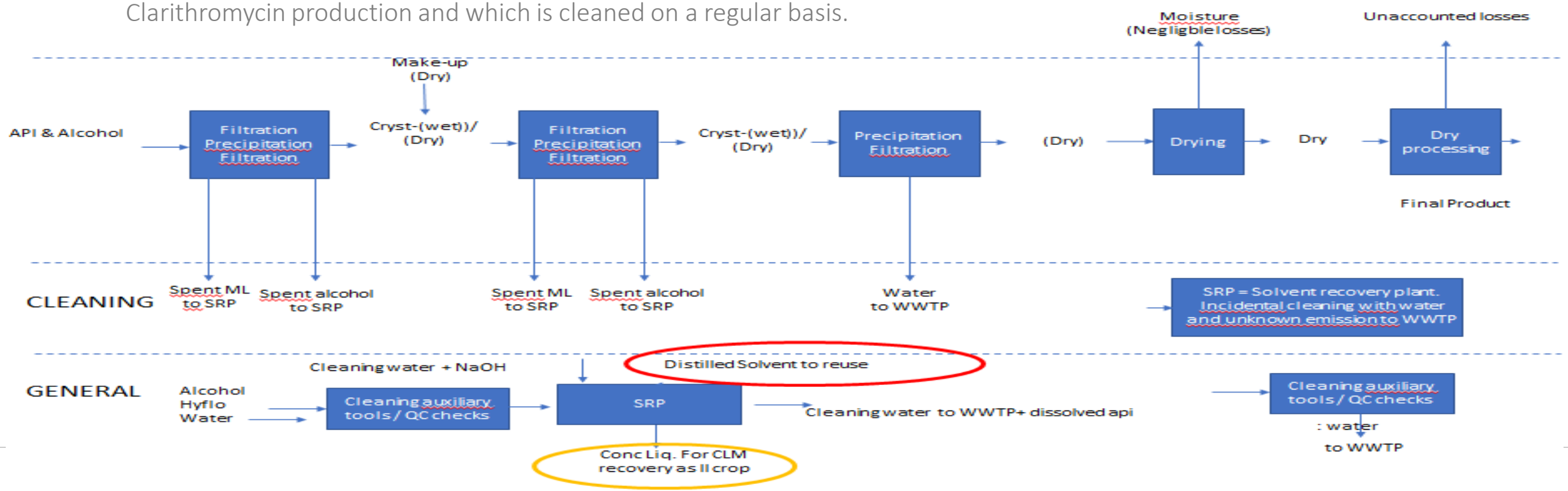
AMR Alliance Recommended PNECs for Risk Assessments

Active Pharmaceutical Ingredient	PNEC-ENV (µg/L)	PNEC-MIC (µg/L)	Lowest Value (µg/L)
Amikacin	N/A	16	16
Amoxicillin	Testing On-Going	0.25	0.25
Amphotericin B	N/A	0.02	0.02
Ampicillin	0.87	0.25	0.25
Anidulafungin	N/A	0.02	0.02
Avilamycin	N/A	8.0	8.0
Azithromycin	0.02	0.25	0.02
Aztreonam	N/A	0.50	0.50
Bacitracin	100	8.0	8.0
Bedaquiline	0.08	N/A	0.08
Benzylpenicillin	N/A	0.25	0.25
Capreomycin	N/A	2.0	2.0
Cefaclor	N/A	0.50	0.50
Cefadroxil	Testing On-Going	2.0	2.0
Cefalonium	21	N/A	21
Cefaloridine	N/A	4.0	4.0
Cefalothin	N/A	2.0	2.0
Cefazolin	N/A	1.0	1.0
Cefdinir	N/A	0.25	0.25
Cefepime	N/A	0.50	0.50
Cefixime	0.18	0.06	0.06
Cefoperazone	N/A	0.50	0.50

PNECs (Mandatory)

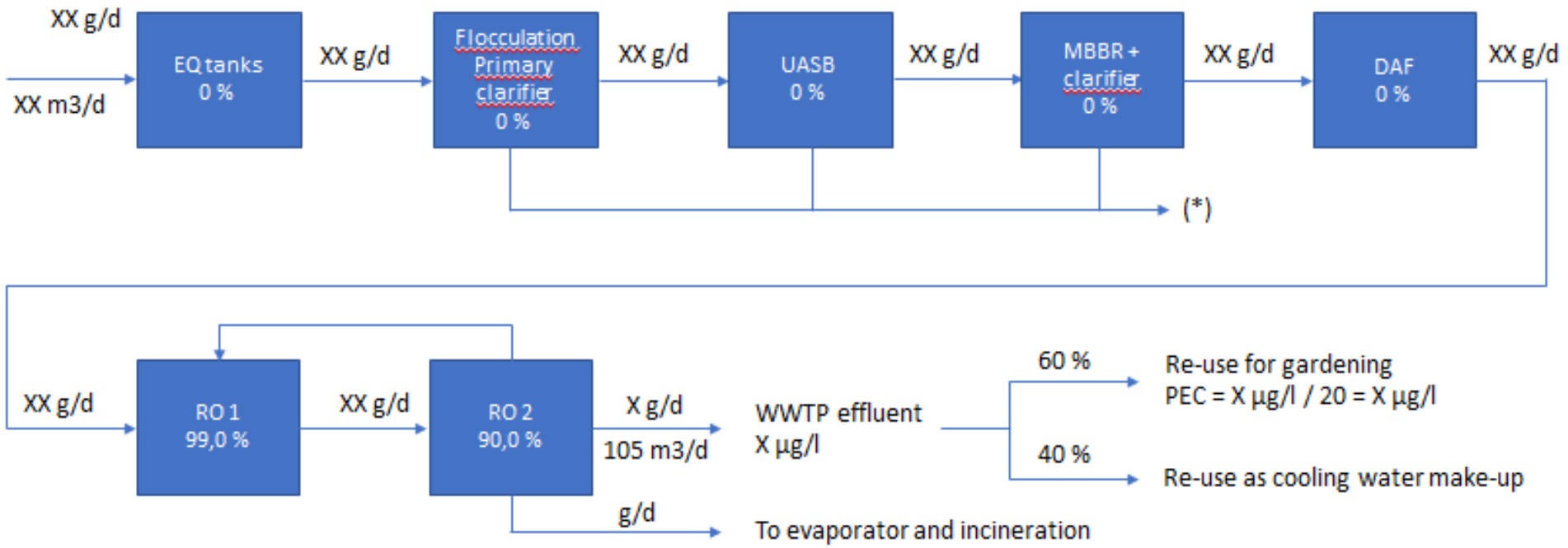
What was our approach? Mass Balance

1. Mass balance estimates were calculated using batch records from previous campaigns.
   - From these batch records, a flow scheme for Clarithromycin production was established indicating possible routes of Clarithromycin loss to water, dust and cleaning solvent (ethanol).
   - The flow scheme was adjusted to accurately represent the actual production process (including losses to water, dust and ethanol). Subsequently the Clarithromycin loss to wastewater was established by compiling a mass balance, for which typical mass data from Production were used.
   - Special attention was paid to the Solvent Recovery Plant (SRP), which receives all ethanol-based washing liquids from Clarithromycin production and which is cleaned on a regular basis.



What was our approach? WWTP

2. After that, the on-site wastewater treatment plant was studied in more detail. There was no data available about Clarithromycin removal in the on site WWTP, neither reliable data on Clarithromycin removal available in literature.
   - Assuming no Clarithromycin removal in the on site WWTP, except for the RO units, a worst case Clarithromycin effluent concentration was calculated.



What was our approach? WWTP

3. WWTP effluent is partially reused as cooling water make up, and partially for gardening purposes.
    - To quantify the ecological impact of WWTP effluent that is reused for gardening, a predicted environmental concentration for groundwater may be calculated based on irrigation rate, the area of concern, the infiltration rate of the soil, hydraulic conductivity and the aquifer thickness.
    - In the Malanpur case, in the absence of site-specific data, a default dilution-attenuation factor of 20 was used to account for contaminant dilution and attenuation during transport through the saturated zone to a receptor.
    - The outcome is then divided by the Clarithromycin PNEC-ENV to yield the Risk Quotient (RQ).

(*) Sludges are send to on site sludge drying beds. After drying, sludges are transported for off-site incineration at the CHWTSDF Facility (Madhya Pradesh Waste Management Projects, Pithampur , Distt- Dhar (M.P.), India).

The on-site sludge drying beds have a concrete lining to prevent groundwater pollution. Leachate is collected and fed to the WWTP. Because of low water solubility, the leachate Clarithromycin load from the sludge drying bed leachate to the WWTP is considered negligible.
(**) Residuals from the evaporator are also transported to CHWTSDF for inceration.

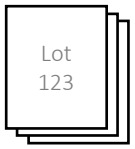
Next Steps

- Investigate alternative effluent disposal, since re-use for gardening might be prohibited in future
- Further evaluate the risk of WWTP effluent infiltration (e.g. what is the environmental impact?
    - Is PNEC-ENV the appropriate reference?
- Quantify losses and/or WWTP removal efficiency and/or effluent concentration during the next Clarithromycin run.
    - Clarithromycin is poorly soluble (0.23 mg/l) which might indicate that the bulk of the API is not present in a dissolved form, meaning that physical/chemical treatment steps might reduce the Clarithromycin more than assumed during the PiE assessment.

Challenges & Considerations

Resources
- Internal
- Third party/consultant

Products
- Multiple strengths
- Different formulations

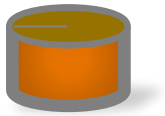


Batch Records
- Adequate representation
- Outliers, gains, campaigns, high yields, etc.

Cleaning
- Method (dry cleaning vs wet cleaning)
- Entire process vs step-by-step

Capture Factors
- Filters (washed vs disposed/wet vs dry)
- Waste (offsite vs onsite treatment)

Flow Data (Not ZLD)
- Location (upstream vs downstream)
- Low flow calculation



Wastewater Treatment
- Availability of “good” data
- Third party reliability

PNECs
- Availability
- Default value?

Suppliers
- Resources
- Understanding/Accuracy

To ask questions, please go to https://app.sli.do/ and enter the event code: #PSCIIndia

Thank you for working with the PSCI

To help the PSCI capability building work better for you, please follow the link (https://www.surveymonkey.com/r/7NWTQTT) under the Survey tab on the livestream webpage to provide your feedback. Thank you!

CONTACT

pscinitiative.org

info@pscinitiative.org

Annabel Buchan:
+44 (0) 7794 557524

PSCI

@PSCInitiative

For more information about the PSCI please contact:

PSCI Secretariat
Carnstone Partners Ltd
Durham House
Durham House Street
London
WC2N 6HG

info@pscinitiative.org

+44 (0) 7794 557 524

About the Secretariat
Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

carnstone
partners ltd