Design and pilot implementation of an EU Early Warning System for chemical risks – DG ENV Pilot project

(Norman General Assembly)

02-12-2020

Contract number – 070203/2019/820480/SER/ENV.B2

Outline

- Objective and main tasks
- EWS evolving features suggestion
- Key features of basic EWS
- Conclusions on comments
- Next phase EWS pilot

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Objective and main tasks of the project

General objective:

- To increase knowledge on emerging chemical risks for the environment and for human health via environmental media
- To provide a basis for improving the policy response to these emerging risks

Context of the study

- Follow-up of the study for the strategy for a non-toxic environment of the 7th EAP
- Launched just after the publication of the green deal
- New momentum with the publication of the chemical strategy

Specific tasks:

- Task 1: methodology governance, key components of EWS
- Task 2: piloting phase
- Task 3: communication tools for authorities and stakeholders

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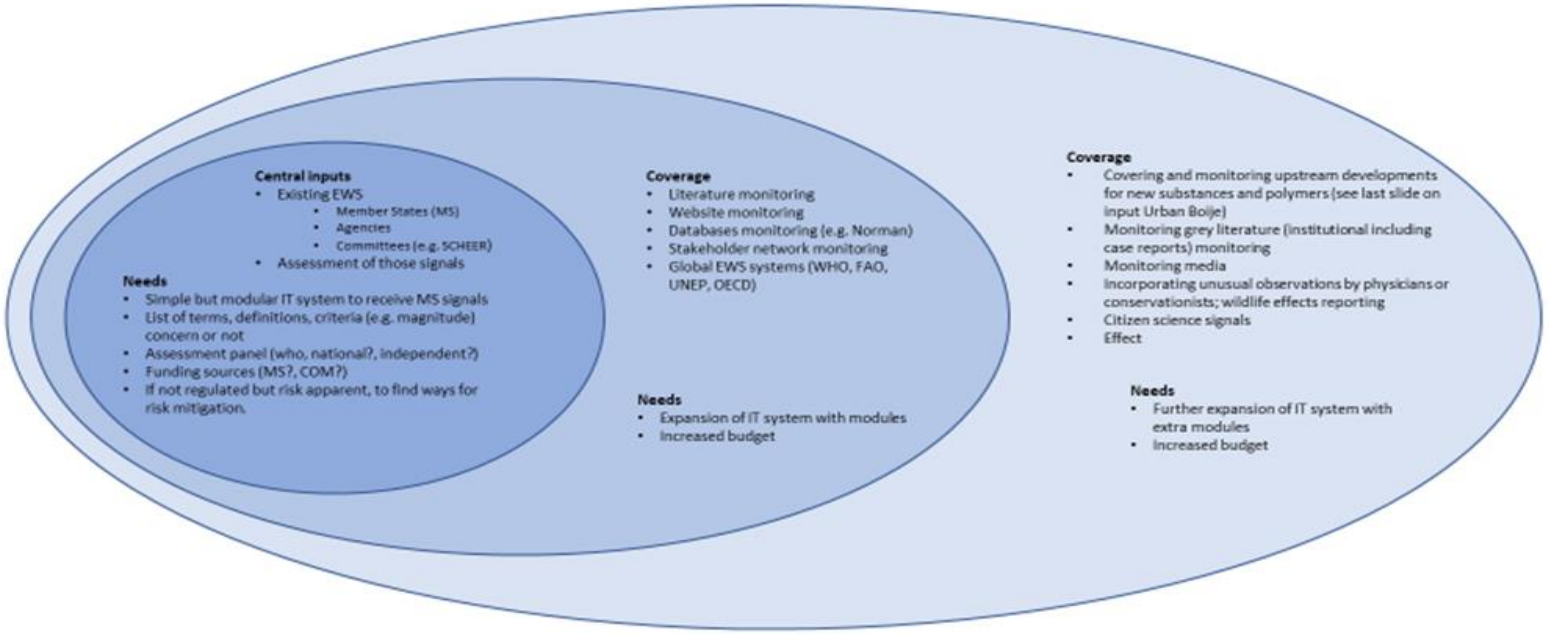
EWS evolving features

Circles going from "**priority central needs**" to "**need to add-on in future**"



Going from central circle outwards: increasing complexity and workability issues and increasing budget needs

On-going discussions with EU actors:

- Concern on the workability of the system and need to further analyse scenarios for capacity and workload (e.g. hundreds of signals)
- A basic EWS will be quite limited and will not be able to cover new substances, trends within the chemical industry such data can only be collected by an advanced EWS

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Scope of basic EU EWS

- Focus on emerging chemical risks to the environment (i.e. emerging chemical risks in different environmental media -air, water, soil- and also their potential indirect effect on human health).
- new substances at research and development stage
- new synthetic substances on the market
- known or unknown substances that have already been present for some time and for which emerging evidence raises concerns
- new scientific knowledge leading to a more critical assessment of the risk
- groups of substances in line with the EU chemicals policy and the chemicals strategy (i.e. grouping rather than single substance assessment and management).
- trends within the chemical industry but also other areas such as population and economic development, energy/circular economy transition but that would require a long-term/foresight approach

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Discussions on scope

On-going discussion on the scope between EU actors:

- Need to address not only single substances but chemical mixtures
- The system should also focus on **effect signals:**
  - Biological monitoring (trends in species occurrence and biodiversity) is currently missing from the picture
  - Suggestion to include emerging chemical risks linked to new susceptible at-risk population or at risk groups due to changes in exposure, emerging pathologies/diseases that change the risk level (e.g. COVID-19)
- Geographical coverage and consideration of scale to be included
- The scope of the project should be "risks to the environment and humans exposed via the environment, not covering risks to workers or consumers via direct exposure"
- more focus non target monitoring (the unknowns), monitoring exceedance of regulatory and non regulatory thresholds (e.g. effect-based monitoring and effect directed analysis).

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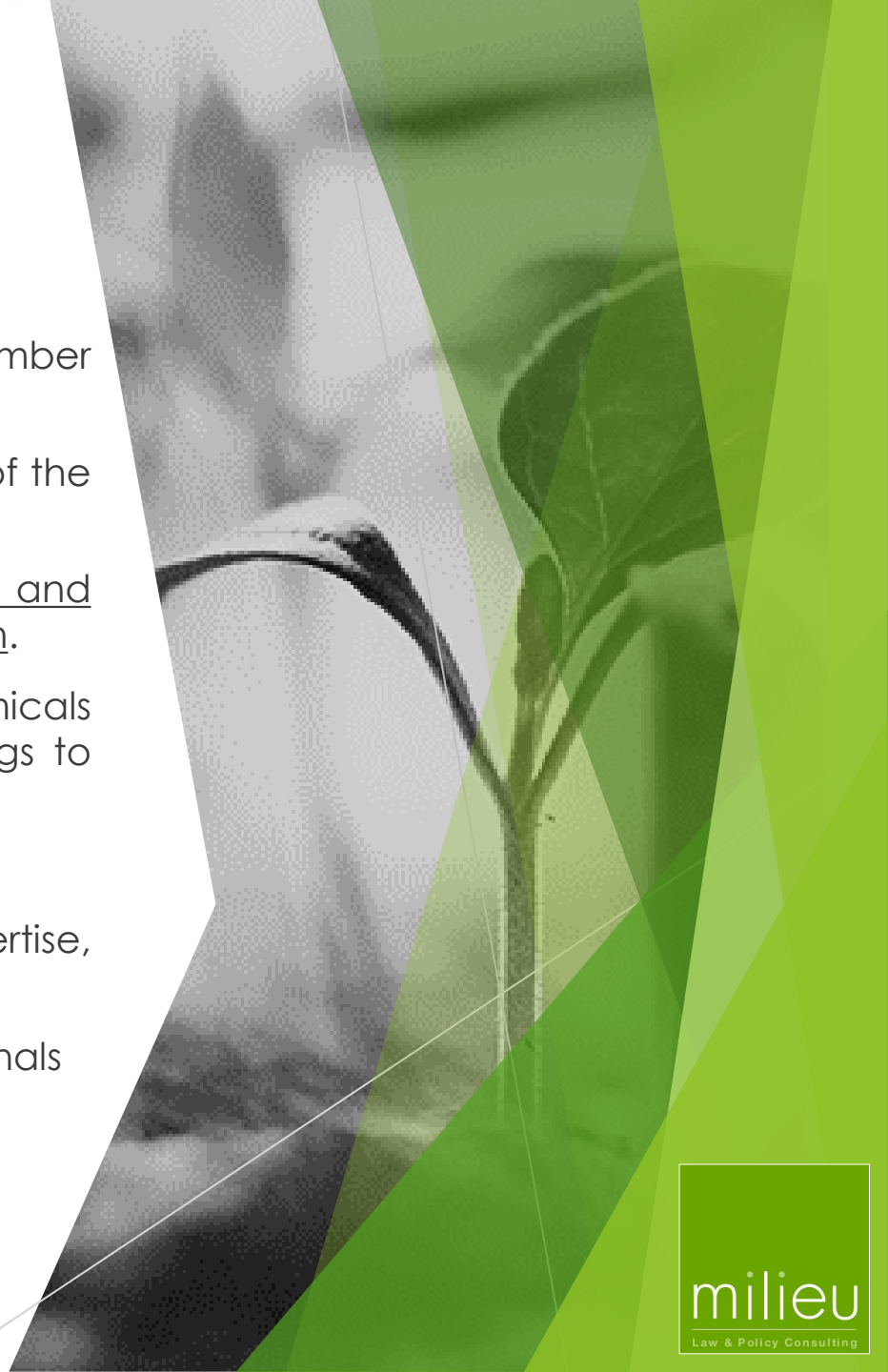
Structure of basic EWS

- EU umbrella system based on the input from national EWS, Member State agencies and EU sources
- Several signal generator leaders based on the different aspects of the definition of emerging risks (EEA, ECHA, NORMAN NETWORK)
- Signal generator leaders play a major role in the coordination and supervision of the process rather than in generating signals as such.
- Secretariat (hosted by DG ENV Sustainable Chemicals Unit/EEA/Eionet) in charge of organising working group meetings to assess signals and propose follow-up actions
- Working group composed of variety of actors
- Working group based on principles of high-level expertise, independence and transparency
- Other option: several working groups according to the type of signals



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Discussions on EWS structure (I)

- Potential layer of complexity entirely on the shoulder of public institutions.
- Already at the "priority central needs" level the practicality of the system is challenging. EWS features should be embedded to the extent possible in existing regulatory and research initiatives (PARC, IPCHEM) and environmental reporting (EEA).
- Significant methodological development will be needed in order to filter and prioritise all the signals for emerging risks
- A more agile/fluid approach directly involving the scientific community (e.g. via scientific societies such as SETAC) could help to filter/prioritize emerging risk
- there should be some consideration given to more automatic detection of signals, e.g. use of AI and text whether in social media or in more classic grey or published literature.
- PARC/EUCHEMRISK could be a possible way of support in the need for methodological development for filtering and prioritizing.
- May be very resource-intensive.
- Risk of silos as signal generator leaders may work in isolation (need of a more general signal leader)

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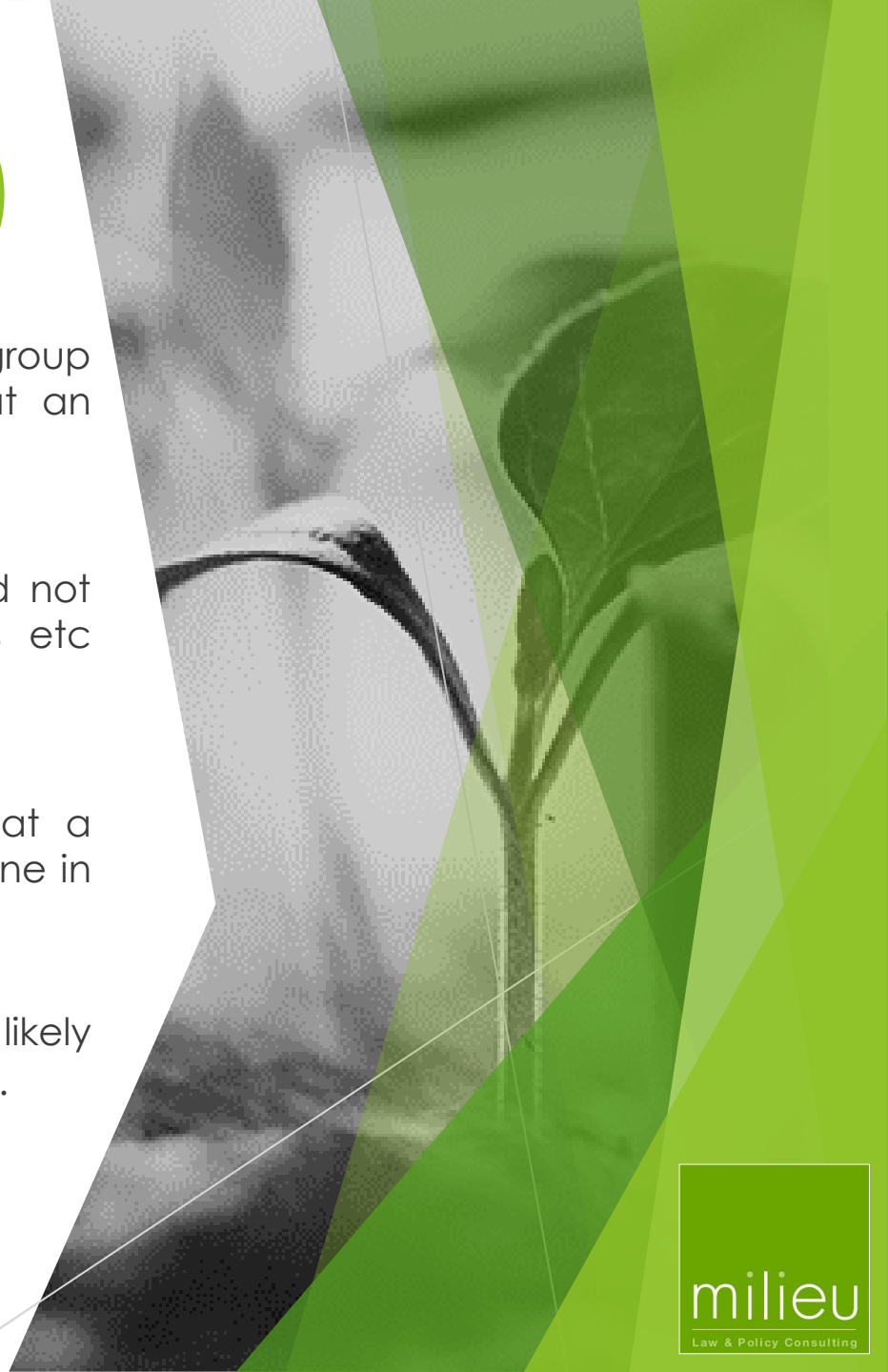
Discussions on EWS structure (II)

- The working group presented would be more of a reference group that could participate to discuss in meetings based on what an expert- working group has concluded.

- A group with representatives from MS and organisations could not function as an operative working group doing the analyses etc needed as a basis for a discussion on prioritisation.

- To be named "Reference group". Working group implies that a significant amount of preparatory and analytical work will be done in this group, which is unlikely to be the case.

- Resource and funding aspects needs to be considered and most likely there will be a need of resources on the EU level if this should work.



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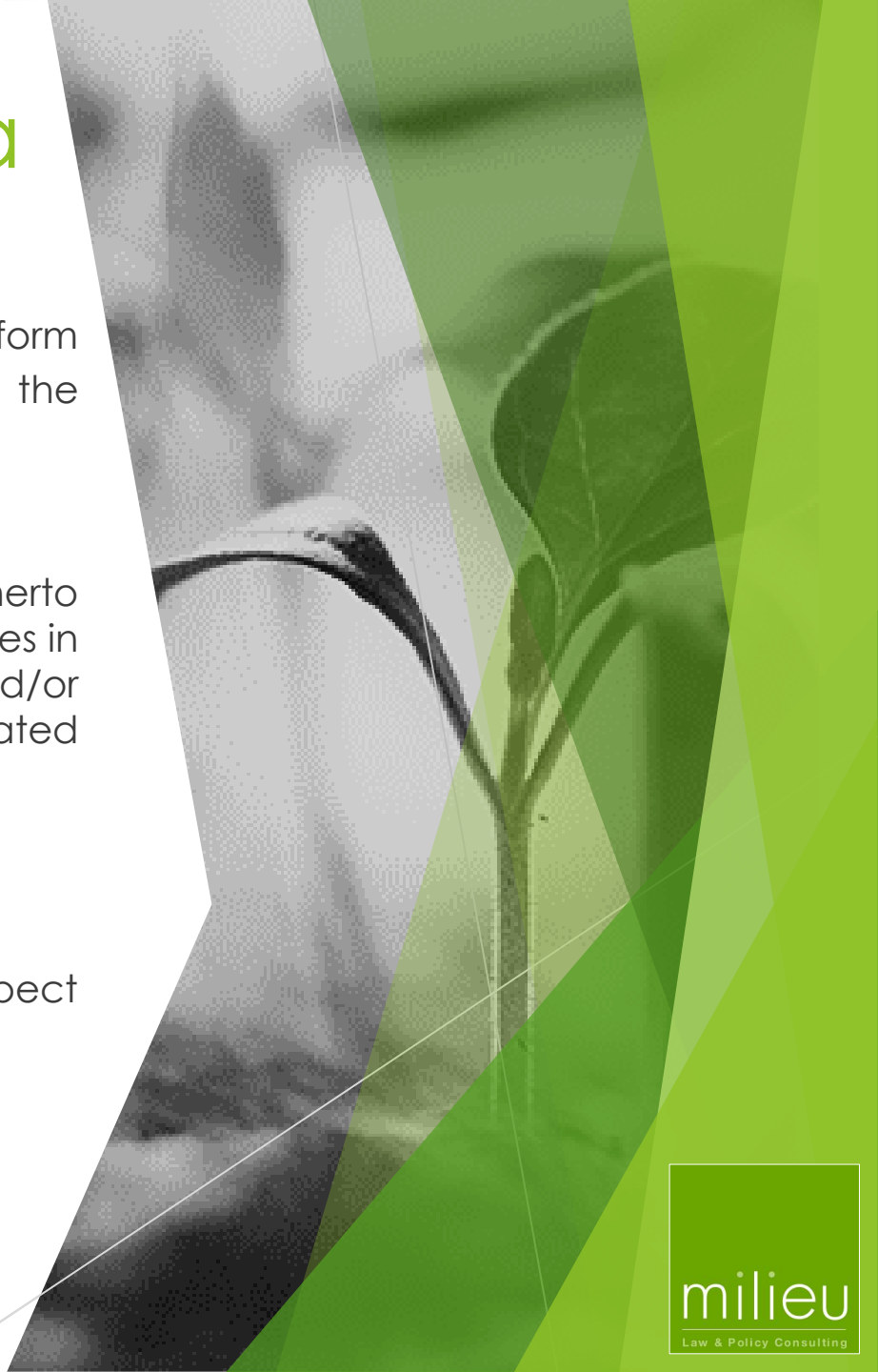
Communication of signals via a submission form

- The designated signal generator leaders would have to submit a form to the Secretariat at DG Environment via an online tool detailing the signals identified

On-going discussions linked to the scope of EWS

- the system should encompass also signals regarding hitherto unknown substances found in environmental or human samples in non-targeted monitoring strategies (e.g. human and/or environmental metabolites of regulated and unregulated substances)
- Chemical contaminants
- Biological signals
- signals as an accumulation of compounds or peaks (suspect screening)



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Rapid alert system

- a simple procedure without signal generator leaders but allowing individuals to directly submit information via an online tool when suspicion of potential emerging risks is identified
- One option would be that information is first submitted to Member State competent authorities who screen the submitted signals and take a decision on whether or not it must be submitted it to DG Environment to feed-into the EU EWS at the confirmatory check phase
- Another option would be to have a direct reporting system to DG Environment without involving Member State competent authorities

On-going discussion within EU actors

- There is a risk of low commitment to report and alert if no legal obligation;
- Confidentiality needs to be clearly defined;
- Not sure whether the number (expected to be relatively low) of emerging chemical risks per year worthwhile of being alerted at EU level would justify the cost for the development and maintenance of such alert system
- To assess this, it would be helpful to provide past examples where such alert system could have been helpful.
- There should be some consideration given to the use of AI in detecting patterns e.g. in social media, text

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Confirmatory check

- For each of the signals received the first step would be to carry out a confirmatory check.
- One option : DG Environment carry out this check. It will have to assess whether the existing EU legislation/measures sufficiently cover the identified signals.
- DG Environment will have to be in contact with other DGs or EU agencies (e.g. EFSA) to gather information on the different EU measures
- This assessment will have to be discussed and reviewed between the members of the working group.
- Another option is to have the confirmatory check done by external independent experts designated through a public tender procedure and then validated by the working group

On-going discussion on who should be in charge of confirmatory check:

- DG Environment, if they have the resources is best placed to ensure continuity, consistency and sustainability of such a confirmatory check.
- The independent expert route is my preferred choice
- The expertise for confirmatory check may reside with MSCAs or Agencies, so assigning it to DG ENV may be inefficient. Another option could be that the confirmatory check is assigned to the most competent body

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Signal reinforcement

- In case current EU measures in place do not address properly this signal, members of the working group would have to decide whether additional information (exposure, hazardous properties, similar cases) and consultation is needed to reinforce the signal:
  - A Member State authority would oversee collecting additional information (e.g. MS rapporteur role).
  - Additional information request through public tender procedures.
  - The signal generator leader will have to carry out further investigations.

On-going discussions

- strengthening of the signal and causal investigations may take quite often years before being able to proceed to the next step of assigning risk scores.
- It could be difficult to get Member States to voluntarily act as a Member State rapporteur.
- automated methods work best for screening larger dataset, but it remains questionable how useful they are to gather additional evidence on an individual substance or a group of structurally related chemicals
- lack of data (hazard and exposure) is a major barrier to "signal strengthening" before initiating regulatory action.
- NORMAN could be involved the signal strengthening phase.

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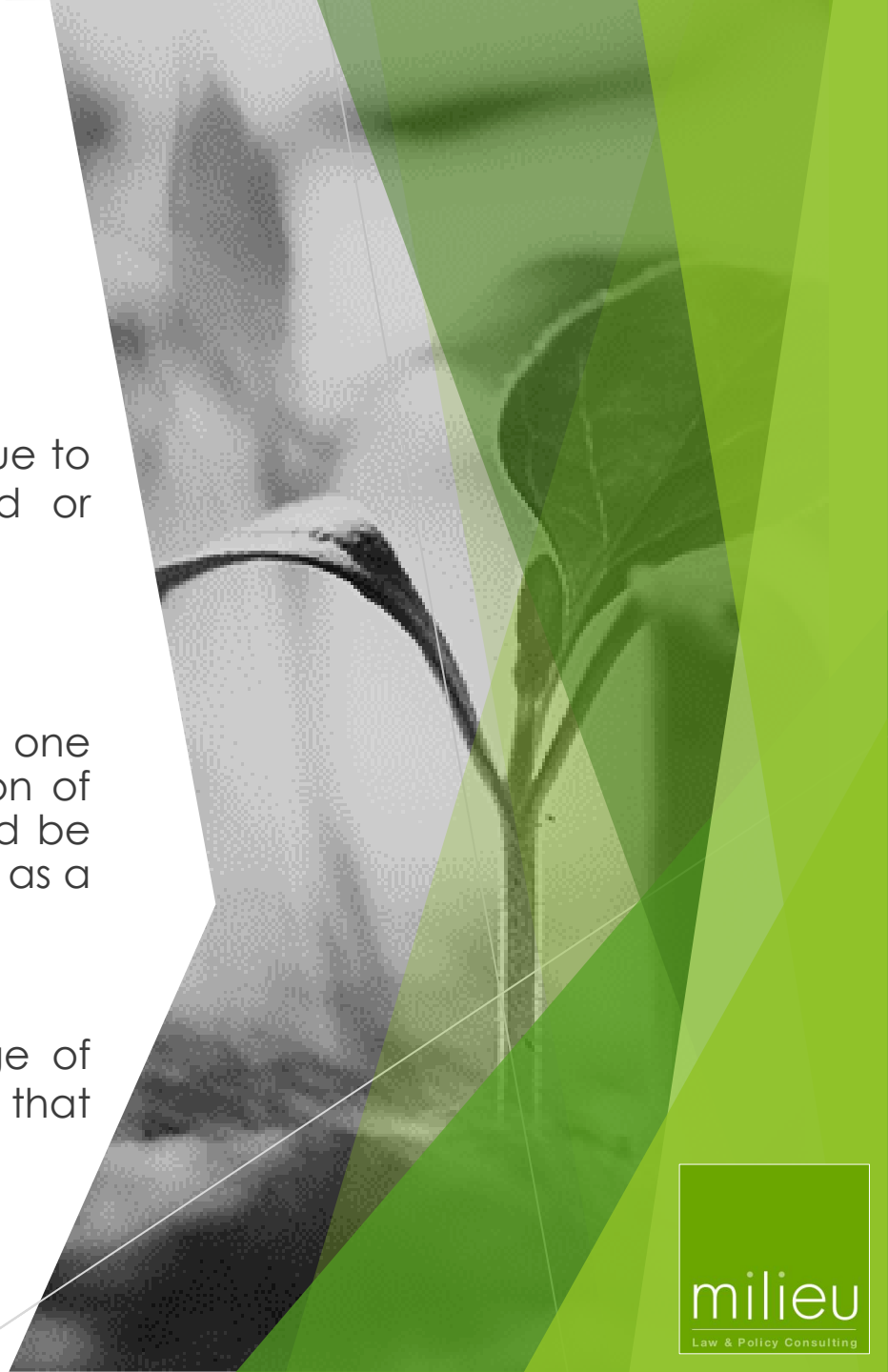
Risk score and prioritization of risks (I)

- Definition chemical risk
    - potential harm to the environment (abiotic and/or biotic) due to exposure to chemical substances (intentionally produced or formed as breakdown products)
- Risk usually defined as a product of exposure and hazard
- From a precautionary principle point of view the focus may lie on one or more hazardous properties as such rather than a combination of hazard and exposure such as persistency. Such a property could be considered as a precursor of risk and a such at least be regarded as a concern.
- Purpose:
    - Evaluation of the information that is gathered at the stage of signal strengthening: identifying the concerns and related to that the follow-up actions
    - If necessary prioritization among chemicals



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Risk score and prioritization of risks (II)

- Criteria needed as a measure to evaluate the potential hazard, exposure and risk

- Characteristics/Drivers to be included but not limited/restricted to
  - Hazard:
    - Persistency, Bioaccumulation, Abiotic accumulation, Mobility, Toxicity (incl. CMR properties)
    - Endocrine disruption
    - Other possible end-points such as
    - GWP and ODP
    - Others?
  - Exposure:
    - Production volume
    - Type of use (wide dispersive, industrial use etc.)
    - Measured environmental concentrations
    - Occurrence (geographical distribution, detection frequency)

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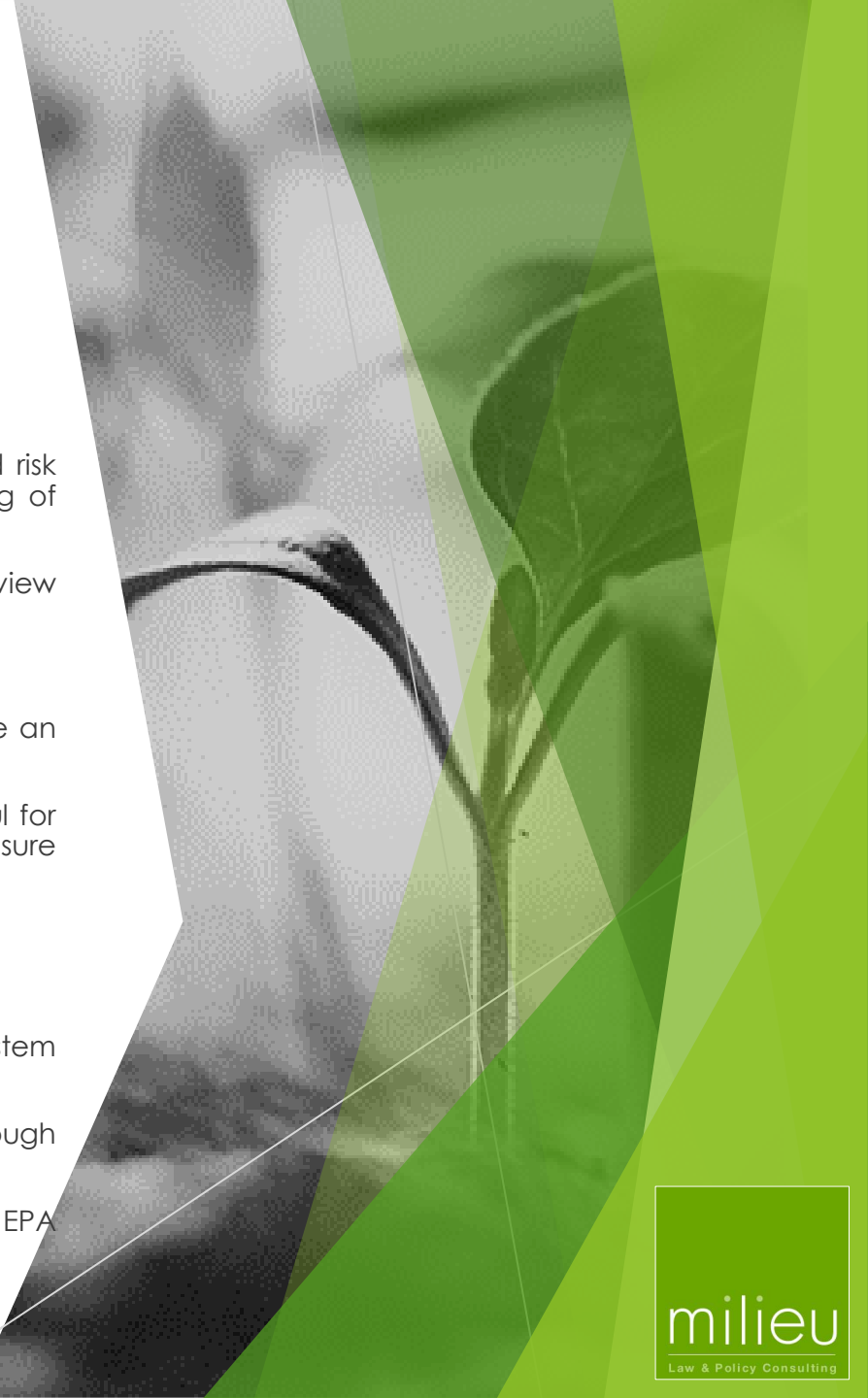
On-going discussions risk score and prioritization of risks



- The term signal should replace the term risk
- Regarding timeliness, it is too late to act on a risk once it is out in the environment
- Suggestions to add quantitative ranges to match the qualitative classes of the proposed risk scores "very low, medium, high etc," to ensure a common and consistent understanding of them.
- Request underlying evidence to justify the score so that a second round may enable to review proposed evidence and eventually readjust the scoring or not.
- A scale aspect is needed
- This is an important process. It will take some time and would suggest that there should be an immediate action to agree a scoring system across the various EU actors
- It is too late to base the exposure on monitoring data, human biomonitoring is more useful for detecting (lack of) effectiveness of the chemicals legislation and confirming whether exposure to chemicals subject to regulatory action is decreasing or not
- Potentially harmful substances to be found before we have monitoring data
- Remaining questions:
  - When defining hazard criteria, how is the information from outside regulatory system used? And is the self-classification made by the industry taken into account?
  - How do you obtain a final risk score from hazard and exposure scores? Is it through averaging?
- The need for a European platform for chemicals, which does not exist now. In the US, the EPA uses dashboards

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Follow-up actions

A list of follow-up actions to be proposed by DG Environment and subject to either a vote or a consensus among the participant to the working group based on the emerging risks prioritised:

- Published in a Commission Communication every year,
- Directed to the relevant EU bodies and subject to discussion to trigger risk management procedures
- To trigger Commission proposals without prior 'fitness check evaluation' replaced by the EWS findings,
- Directed to enforcement authorities when emerging chemical risks are a direct consequence of non-compliance with environmental/chemical legislation at EU and national level

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On-going discussions on follow-up actions

- Any process needs to be as well defined as possible, minimising the risk of blurring or suppressing the message/signal from the EWS.
- Follow up actions to create further evidence such as liaising with DG research and academia at European level
- The drafting of a Commission Communication is a highly political exercise which would likely involve undesired/inappropriate filtering, based on other judgements than potential risk of the substances involved.

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Formalization of the EWS

To ensure visibility and permanency, core elements, procedures to be detailed and described in an EU official document such as:

- A Commission decision
- A Commission Regulation

On-going discussions

- The current policy ambition is towards simplification and consolidation (for good reasons) and the proposed approach may not be politically feasible. Softer alternatives may be needed.
- Without any legal binding the system will depend on the good basis of voluntary contributions of all the players and this will need time to be built and for all to see the added value of collaborating and sharing.
- Some evidence streams described in this EWS (except rapidly emerging risks or accidents) could be better coordinated and incorporated in policy evaluation exercises and feed this way into the policy cycle.

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EWS potential features in the future

List of potential features of such system:

- Taking up of signals from upstream actors operating (pre-EU-EWS) signal-generating systems
- Results flowing into an EU-hosted secure web-based data-entry portal
- Automated system
- Unifying signals using unique chemical identifiers
- Strengthening signals with similar signals
- Preliminary risk assessment/risk screening
- Proceed to manual curation and evaluation if risks (RCR > 1) are predicted.
- Promulgate to prepare a warning for the competent authorities if RCR > 1 is endorsed by manual experts' assessment.
- Citizens science as a source of information

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On-going discussions on EWS potential features in the future

- EFSA within a MS grant has developed a platform for MS to collaborate/ exchange on emerging risks. Related information can be found in the EFSA dedicated webpage on emerging risk methodologies: http://www.efsa.europa.eu/en/topics/topic/emerging-risks
- Need to strengthen existing IT systems and not add another one (e.g. automated system to flag PEC or PNEC exceedance or increasing trends in monitoring could be implemented via IPCHEM)
- The automated system is important but will also need human oversight.
- Citizen science is an interesting area, perhaps lower quality data but no doubt valuable when combined with other sources of data.
- The study already identified a number of existing IT systems. Investing in yet another portal may carry unnecessary costs and complexity. We recommend assessing the current systems (IPCHEM etc.), if they could natively host signals with simple modifications.
- To laise with project on Common open platform for chemical safety data

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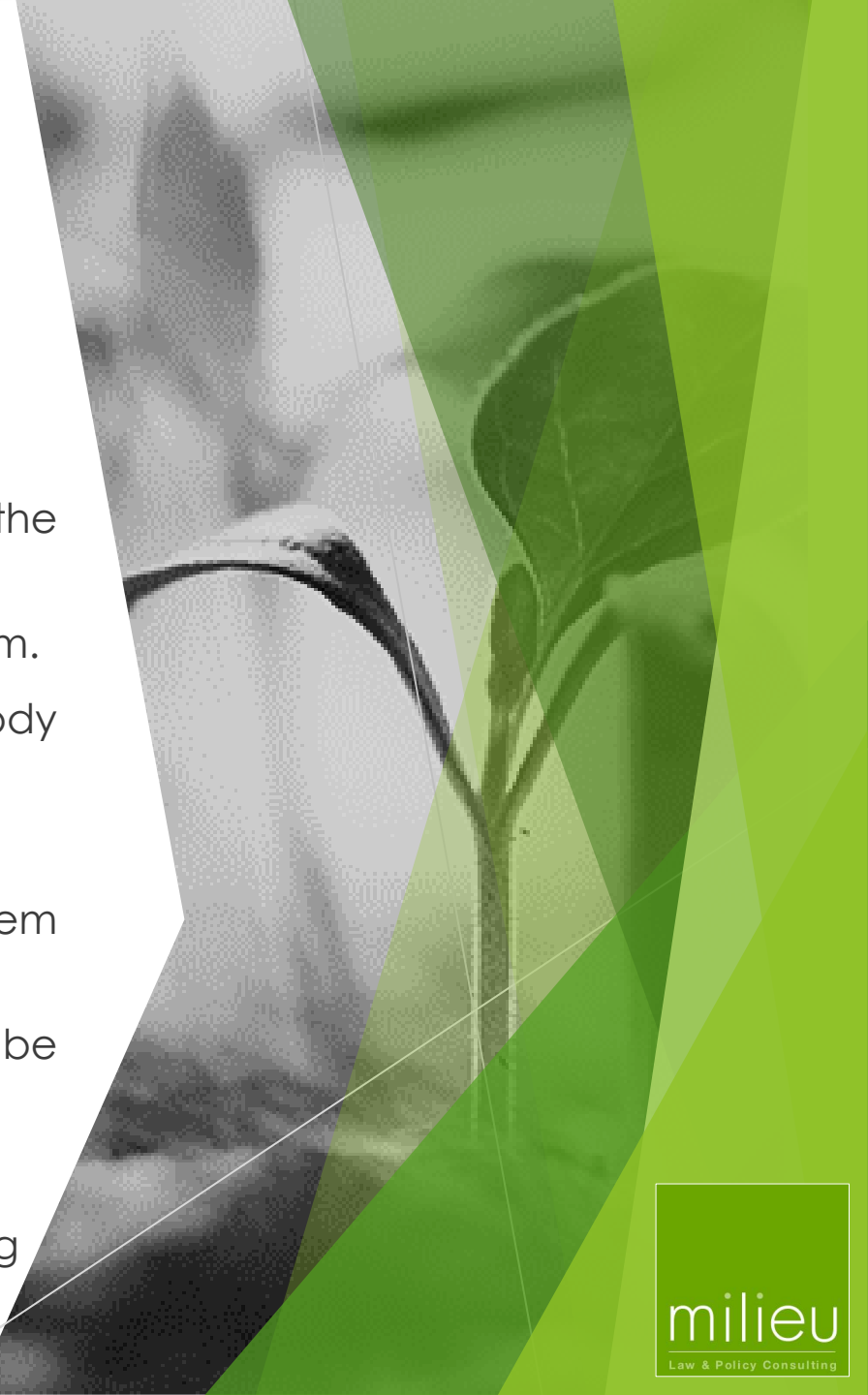
Main points of discussion



- Question raised about the governance/workability of the system;
- Questions regarding the signal strengthening/prioritization, and the kind of signals to consider;
- Questions on the temporal and spatial operating range of the system.
- EWS should be "lean and mean" and no new heavy institutional body should be developed.
- The new EWS should build upon an already existing system
- a voluntary system is in the end not workable, and that the system should be institutionalized, including legislation
- Resources and budget involved was a concern and should be allocated to the members of the system to be developed.
- Need to have a clear definition of risk.
- Clearer description of the problems that the system would be solving

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Next phase: EWS pilot (I)

- Development of a template to identify signals (**beginning of December)**
- Identification and contact of scientific experts: **(Mid-December)**
  - Involvement in early warning systems on chemical emerging risks.
  - Academic research and publication in chemical risks for the environment.
  - Adequate geographical repartition across the EU.
  - Adequate repartition according to expertise in different exposure pathways and environmental impact
- Completion of template by scientific experts/organizations (up to 3 signals maximum) **(last week of January)**
- Compilation and preparation of a document summarizing all signals identified **(first week of February)**

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Next phase: EWS pilot (II)

- Selection of up to 10 signals (need to develop selection criteria) **(second week of February)**
- Focus groups/workshop to discuss these signals and prioritisation process **(third week of February)**
- Preparation of first draft recommendations on follow-up actions **(beginning of March)**
- Focus group/workshop to discuss and validate recommendations **(end of March)**
- Finalisation of recommendations on potential follow-up actions **(mid-April)**

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Thank you for your attention

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