

COMMITTEE ON CARCINOGENICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT (COC)

Discussion paper following facilitated COC-COM workshop on horizon scanning

Introduction

1. Horizon scanning brings together insights from diverse disciplines to identify issues that are (1) likely to have a positive or negative impact on the work of COC, as well as COM and COT, in the coming years, and (2) are not well known to the public or wider scientific community or are likely to undergo a substantial 'step-change' in their importance or application (Sutherland and Woodroof, 2009). Horizon scans are an effective means of pre-emptively identifying emerging issues facing Government Departments and Agencies in terms of the advice they may require from COC.
2. Delivery of such a programme of horizon scanning will provide the insights that can be applied to Committee business (and if necessary, any of its associate organisations or partners) to look ahead, analyse what is seen, and use these insights to strengthen strategy, policy, technological preparedness, and operational goals and approaches. This work will help to future proof the committee activities – enabling realisation of emerging trends, and building the capability of colleagues to adopt future thinking to enhance their work.
3. In order to deliver this workstream a joint COC-COM Horizon Scanning facilitated discussion was held on the 9th October 2023. This is a summary report of the outcomes and decisions reached. A series of potential work-streams have been identified:
 - a. It was agreed to develop a continuous programme of regular horizon scanning to identify and disseminate emerging issues (both positive and negative) on the short-, medium- and long-term horizons, with reporting at intervals to be agreed with the Secretariat;
 - b. A method was agreed to assess and prioritise the importance/likelihood and impact of the emerging issues identified in [a] above;
 - c. In the future a programme of deep dive studies will be developed to investigate the current state of science/evidence and possible future developments and determine the implications of issues identified as high priority (by respective committees).

Understanding Committee requirements

4. Through undertaking regular horizon scanning activities to produce a prioritised series of short briefs that describe insights around emerging issues relevant to COC, as well as COM and COT, in the short-, medium- and long-term, a programme of activities can be tailored based on an understanding of the trends, challenges and opportunities relevant to COC. The workshop addressed some of the priority areas using a combination of SWOT (Strength, Weaknesses, Opportunities and Threats) analysis and STEEPLE (Social, Technological, Environmental, Economic, Political, Legal and Ethical) analysis and sought consensus on format and prioritisation approaches.

5. Horizon scanning identifies emerging issues that are on the periphery of current thinking and planning, and provides an early assessment of the trends, challenges and opportunities, to identify gaps in current knowledge and potentially emerging risks. Future emerging issues (termed insights) will be assessed in terms of their relevance to Government Departments and Agencies policy and goals in so far as they may link with COC activities.

Horizon scanning facilitated workshop

6. Horizon scanning is a technique used to identify emerging issues that may have an impact on COC. Online databases from a large number of sources, coupled with expert elicitation, will be used to develop structured scans. To help focus horizon scanning outputs, the workshop was needed to identify key drivers.

SWOT summary narrative

7. A collective SWOT analysis was undertaken that examined the key drivers for focussing and adopting horizon scanning within the committees. The outcomes from this activity are presented in Figure 1. The key strengths were the shared breadth of experience within the “Committees” including the secretariat and other support available. The principal willingness to engage within the committees without competing for time and the ability to utilize new and emerging knowledge to enhance and to develop expertise that would assist with work and programme planning. Consideration of the weaknesses acting largely upon the committees included conflicting priorities and lack of time, the limited resources available in specific areas, the management of biases. Noting that recruitment to the Committees is poor and the remit very broad.

This is a background paper for discussion.
It does not reflect the views of the Committee and should not be cited.

S Strengths <ul style="list-style-type: none"> • Breadth of expertise • Secretariat support • Other Committee support • non-competitive collaboration • Willingness to engage in HS • Helps work programme planning • Members are at forefront of fields – ongoing expertise 	W Weaknesses <ul style="list-style-type: none"> • Time • Conflicting priorities • Breadth of expertise – limited person resources in some areas • Biases • Remit of Committees is broad • Recruitment to Committees poor
O Opportunities <ul style="list-style-type: none"> • Capture emerging issues and improve responsiveness of Committees • Differentiation of ‘importantness’ of emerging issues • Regulatory freedom following Brexit • Associate member engagement • AI 	T Threats <ul style="list-style-type: none"> • Drawing undue attention to issues • Lack of next generation expertise to inform Committees • Anti-recognition of regulations • AI

Figure 1 SWOT analysis of key requirements for the use of horizon scanning by Committees.

8. Whereas the analysis of the Strengths and Weaknesses in a SWOT tend to focus on internal organisation the opportunities and indeed the threats are often extended through changes in the external environment.

9. The key opportunity was to stay informed of emerging issues and as a consequence improve the responsiveness of the Committees. One pivotal aspect was the ability to rank the relative importance of issues either emerged or emerging through a more detailed analysis. One specific area for consideration was the use of Artificial Intelligence (AI) within the Committees. One significant outcome was the opportunity for greater regulatory freedom as a consequence of the UK leaving the EU. Drawing undue attention to issues raised through horizon scanning was considered a threat, alongside a lack of next generation expertise to inform Committees. There was recognition that regulations could be considered in a negative/ non-regulatory future and finally AI featured also as a threat.

10. The participants also considered another SWOT activity (see Figure 2) considering some potential emerging issues. Considered by the group as strengths were AI and other emerging new technologies. The Committees’ willingness to change approaches and adopt horizon scanning and build on the outputs and finally the benefit of enhanced communication. The weaknesses, again considered AI, the lack of expertise in emerging technologies, for example, in silico model development. The fact that regulatory change is slow, the opportunity to adopt and innovate are

therefore hindered and not unsurprisingly that communication can be a weakness when it is poor.

11. The external opportunities were again AI this time seen as a means to improve certain aspects of committee work. The opportunity to bring on early career “toxicologists” or other experts as future members or possibly through intern schemes etc. The ability to engage with regulators at an early stage of development in any emerging issue. The opportunity to realise better use of Novel Approach Methodologies (NAMS). The ability to enhance communications between committees in particular through shared use of horizon scanning outputs. The opportunity that independence from the EU could enhance the adoption and implementation of NAMS in the regulatory system that might also include other new technologies. Finally, the committees considered that AI might also be a threat in terms of evidence provision, the ability to evaluate new technologies could also be hindered by insufficient knowledge to provide reliable evidence evaluation of future technologies. The recognition of social and political pressures on decision making and regulatory acceptability were also considered a threat. Finally, poor or ineffective communication was deemed a negative.

S Strengths <ul style="list-style-type: none"> • AI • New technologies • Willingness to change approaches • Communication 	W Weaknesses <ul style="list-style-type: none"> • AI • New technology /lack expertise in emerging technologies e.g in silico model development • Regulatory change is slow • Communication
O Opportunities <ul style="list-style-type: none"> • AI • Bringing on early career members including interns • Engage with regulators at early stage • NAMs • Communication • Brexit allows faster incorporation of NAMs and other new technologies 	T Threats <ul style="list-style-type: none"> • AI • Evaluation of new technologies – evidence evaluation • Political / social pressures • Communication

Figure 2 Outcomes of a focussed SWOT activity to consider emerging insights.

Committee preparedness

12. In a further exercise the Committee considered the stage or preparedness versus likely impact for several emerged issues. Figure 3 depicts a summary

representation of the considered insights (risks) in terms of committee preparedness to respond versus predicted likely impact to the work of the Committee. For each scenario dependent on the state of preparedness there are decision options. There may be an imminent need to act now to ensure a potential risk is mitigated, or it may be that the likely risk is further into the future and being prepared to act is a more likely option. If a risk is further on the horizon, then keeping a watching brief may be the best option. Doing nothing for prioritised and agreed risks/ insights to the

Act now	Prepare to act	Watching brief	Ignore
Invest in improving resilience, transfer risk to third party	Incorporate in investment strategy, invest in research, up-skill staff	Monitor, invest in research	N/A!

Committee is not an option.

13. During the exercise four insights were selected (Figure 3) NAMS, where it was felt that the committee were moderately prepared and that the use of NAMS may have high impact. For understanding the significance or consequences of biological therapeutics, also referred to as Biologicals (those classes of medicines which are grown and then purified from large-scale cell cultures of bacteria or yeast, or plant or animal cells)¹ it was considered that the Committee was highly unprepared and such could have moderate impact [note from the Secretariat – biologicals will be on the edge of COC remit, as medicines they are more likely to be assessed by MHRA and its Committees]. The role of AI once again was considered by the Committee, as being of potential high impact with the Committee being highly unprepared to deal with the consequences; alongside the final insight the “consequences of unplanned unknowns” which are likely of high impact and again Committee is unprepared for.

¹ Biologicals are a diverse group of medicines which includes vaccines, growth factors, immune modulators, monoclonal antibodies, as well as products derived from human blood and plasma. What distinguishes biologicals from other medicines is that these are generally proteins purified from living culture systems or from blood, whereas other medicines are considered as ‘small molecules’ and are either made synthetically or purified from plants.

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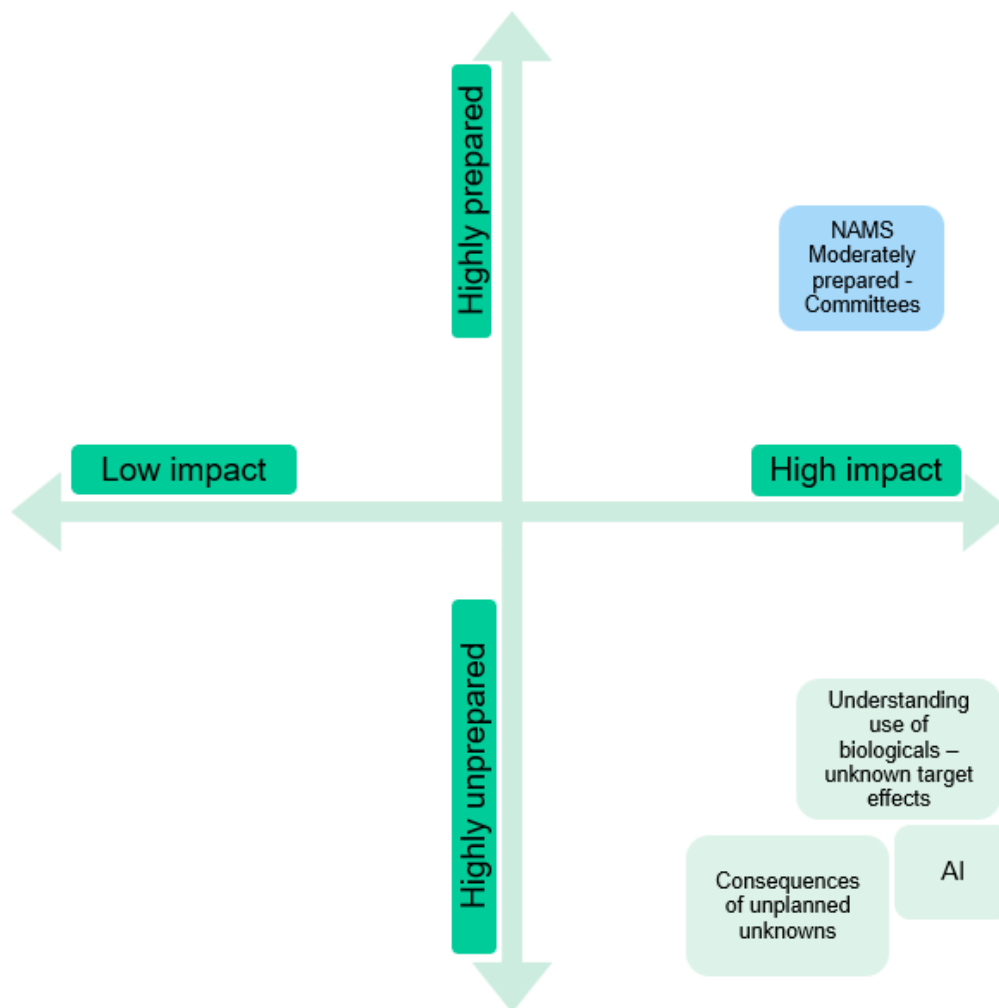


Figure 3 An assessment of Committee preparedness versus impact of four insights.

STEEPLE Analysis

14. The Committees participated in a STEEPLE analysis. STEEPLE analysis is a planning tool used in this case to consider external drivers to help prioritise and focus insights for horizon scanning. A STEEPLE analysis also considers current government policies, employment laws, political stability, and more through a macro-environmental lens. Conducting the STEEPLE analysis can help committee understand the external environment to better predict future impacts in their planning.

15. The STEEPLE analysis framework overlaps with other research tools, such as STEEP (Social, Technology, Environment, Economics, Politics) and PESTEL (Political, Environmental, Social, Technology, Economics, Legal) analyses but includes legal and ethical factors. It differs from a SWOT analysis in that a STEEPLE analysis focuses on external factors whereas a SWOT analysis typically focuses on internal factors.

16. The purpose of using STEEPLE is the wide breadth of scanning drivers, and not simply compartmentalisation of the themes.

17. The following headers comprise the STEEPLE framework:

- **Economic:**
Economic factors are a significant part of the STEEPLE analysis and encompass changing exchange rates, new tariffs, the GDP, and more.
- **Environmental:**
Environmental factors or ecological factors might include the availability of natural resources and climate change, which can affect committee decisions.
- **Ethical:**
Ethical factors measure the marketplace's attitude toward corporate social responsibility, moral standards, and accountability.
- **Legal:**
Researching legal factors means diving into court decisions, trade unions, and other regulations that can affect day-to-day and decision making.
- **Political:**
The political situation can impact on all aspects of Committee's work.
- **Social:**
Social factors might include population growth rates, social mobility, and population demographics. For the latter, understanding what genders, education levels, age distributions, and other factors are essential to making future decisions.
- **Technological:**
Analysis of the technological changes/ challenges that will help inform how new technological factors can streamline or impact on committee business.

18. Figure 4 summarises the outcomes of the focussed STEEPLE analysis. The items are not ranked or prioritised. There are several significant drivers presented. Perhaps most surprising is the considerable number of entries under "Social" with themes ranging from increasing societal challenge and anti-regulation, through climate change and animal testing to ensuring that the committee makes best use of social media communications to share opinion and outcomes. Perhaps prior to the meeting, the importance of engaging and communicating with society was less-considered in the work of the Committees. Technological drivers revolve around the use of AI and big data sets, the recognised issue of NAMS and the ever-present aspects of climate change. Environment also featured echoing climate change concerns but also a lack of environmental perspective in the form of ecotoxicology insights to the Committees work. Under the Economic header, climate change repeats gain, alongside the consideration of regulatory overburden and maintaining industrial competitiveness. Political drivers include being able to challenge decision making, disruptive political change, and whether politicians remain passive or reactive. Climate change features once more. Under Legal, the challenge to decision making and animal testing are highlighted along with climate change. Under ethical drivers the role of devolution and country specific ethics and wider consideration are

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considered, along with the need for an industrial perspective. Animal testing and climate change feature again.

19. In terms of using these key drivers, it was considered by the group that the implications of social and ethical considerations may be of higher relevance to Committee decisions in the future. The level of repetition across the key drivers for particular themes such as climate change, animal testing, challenges to decision making reflect the current and growing societal voice around these key issues.

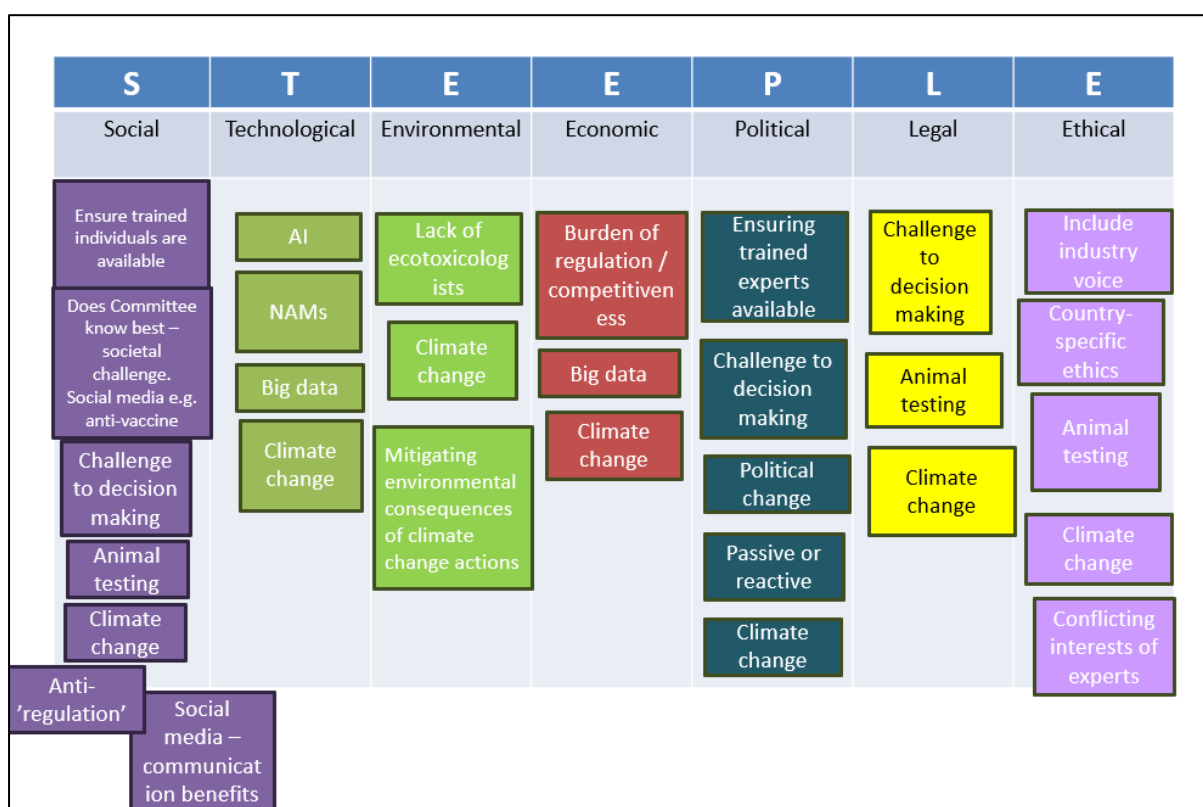


Figure 4 The summary outcomes of the STEEPLE analysis identifying external key drivers impacting the work of the Committees.

Prioritising the insights

20. Horizon scanning can yield huge amounts of data and needs to be filtered to identify the most important insights and prioritise effort and resources. A common framework helps compare insights that are difficult to compare e.g. risks with opportunities.

21. Prioritisation of insights is indicative of importance rather than risk alone. The prioritisation criteria used may need to be adapted for each organisation and this workshop exercise enabled the Committees to agree decision criteria that are relevant. It was important that only a limited number of criteria were adopted to avoid overwhelming the decision maker with data. The insights will be developed as narratives to provide context (numerical assessments alone miss important context required for decision making).

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22. The output is usually a regular update (in the form of a briefing note such as CC/2022/07) featuring 10-20 insights organised by driver and presented in a manner suitable for all levels of understanding of emerging risk. Insights could be presented in an accessible, easy-to-read format (250-word limit) comprised of:

- A title which is both informative and engaging.
- A description of the 'insight' or issue directly or indirectly related to health.
- An analysis of the implications or 'what this might mean' for the Committees.
- A link to further sources of information and a label that indicates the type of evidence source cited.
- A risk prioritisation score.

23. It was agreed that the horizon scanning insights would adopt a similar format to that presented in Figure 5.

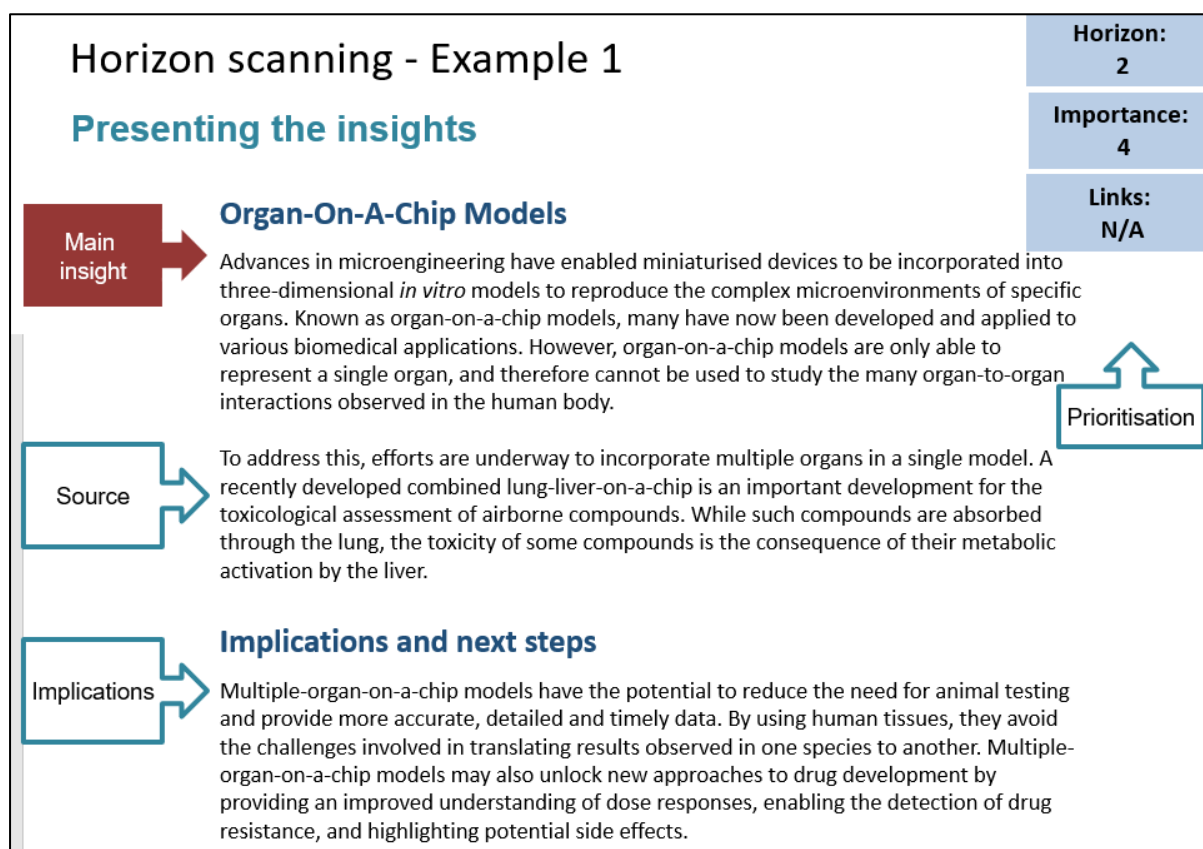


Figure 5 A typical format for presenting insights as agreed during the workshop.

Horizon scanning prioritisation

24. A consistent, standardised scanning method is used to generate a list of emerging issues at the earliest stages of concept and testing that may have implications for the Committees. Two to three insights are selected from each of the drivers of change for each publication. A final decision about the insights to include will be reached by consensus, as is the case in many horizon scanning systems

(Douw and Vondeling, 2006), but will be based around criteria such as: relevance to COC; novelty; short-, mid- and long-term implications; and lessons learned from other examples. The insights are then sense checked across all relevant systems, as well as with colleagues across Government Departments and Agencies as relevant.

25. Insight analysis consists of a prioritisation process and consideration of the implications for COC and the Secretariat. A multi-criteria decision analysis is used to give each insight an importance score to serve as an indicator of the likely level of risk and/or opportunity associated with each insight. This consists of a semi-quantitative assessment process adapted from Prpich et al. (2011) and conducted potentially by committee members. Each insight is presented to a panel member in isolation and a nominal score between one and five is assigned by each panel member for the likelihood of the insight affecting the client (not likely = 1, moderately likely = 3, very likely = 5). A score between one and five is assigned for the scale of impact on the selected topics/ driver, for example; on the environment, on the economy, and on society (low impact = 1, moderate impact = 3, high impact = 5). The range of scores is then presented to the group, discussed and debated and the panel then re-scores the insight, again in isolation. The score used to calculate importance is the average of the second scoring. The importance score is determined by taking an average of the agreed criteria, e.g., health, social and economic impacts, and multiplying this by the likelihood of occurrence, with final scores ranging from 1 (low risk/opportunity) to 25 (high risk/opportunity). This score is subjective and intended only to distinguish between the issues identified in a relative sense. A time horizon is also assigned to each insight to indicate the period of time in which the insight is likely to first have impact on the client (short: 1-3 years, medium 2: 4-10 years, long 3: 10+ years). Whilst these time horizons can be useful for planning purposes, they should not be used as an indicator of when action is needed. An event likely to occur in 15 years may still require action(s) now in order to mitigate it. The scoring is approximate due to the inherent uncertainty and complex interactions; however, these ratings would be indicative of importance, and should help to guide intervention strategies or future research needs towards the highest priority issues.

26. The Committees agreed during the workshop the following criteria (three priority drivers) would be considered for the prioritisation of insights:

Social impacts	(1= low, 5 = high)
Economic impacts	(1= low, 5 = high)
Environmental impacts	(1= low, 5 = high)

The likelihood of these impacts being seen in the UK
(1= unlikely, 5 = likely)

The time horizon (point at which the main impacts would be seen)
1 = 1-3 years
2 = 4-10 years
3 = 10+ years

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27. The Committee agreed to adopt the following prioritisation scheme based on importance.

Importance score = $\frac{(\text{social} + \text{economic} + \text{environmental})}{3} \times \text{likelihood}$					
Overall importance score	Impact			Likelihood	Time horizon
	Economic	Environmental	Social		
11	3	4	4	5	1

Linking horizon scanning into Committee needs (understanding the opportunities and threats)

28. For the outcomes of the horizon scanning to be of value to the Committee Secretariat and Sponsors, the mechanisms of their adoption into the 'business' needs to be understood, accepted and then embedded within the committees. There is a need, therefore, to facilitate this process through interaction with the secretariat and committees in order to evaluate and understand how the outcomes of the horizon scanning might be adopted or incorporated into any future activity/strategy.

Next steps

29. The next step is to undertake some scanning and bring some prioritized insights to the Committee for discussion.

Questions for the Committee

30. Members are invited to consider the summary of the joint COC-COM workshop and in particular:

- i. provide comments on the summary or for future consideration
- ii. highlight any areas that have come to their awareness since the session

**IEH Consulting under contract supporting the UKHSA COC Secretariat
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Acronyms

NAMS	Novel Approach Methodologies
PESTLE	Political, Environmental, Social, Technology, Economics, Legal analysis
SWOT	Strength, Weaknesses. Opportunities and Threats analysis
STEEP	Social, Technological, Environmental, Economic, Political, analysis
STEEPLE	Social, Technological, Environmental, Economic, Political, Legal and Ethical analysis