Keynote speech by Mr Geert Dancet, Executive Director, European Chemicals Agency

'WSSD 2020 goals – are we going to make it?'

2017 Helsinki Chemicals Forum

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Dear colleagues,

It gives me very great pleasure to join you once again at this Helsinki Chemicals Forum. It is a perfect opportunity every year to take time out to talk about the wider issues of concern to us all. And it's a wonderful occasion too to have all of us in one room together - from industry, regulatory authorities, international organisations and civil society. Because, although we work for many different organisations, we have one common objective – to make our world safer.

At the end of this year, I leave my post as the Executive Director of the European Chemicals Agency (ECHA). I thought that I would take this opportunity to reflect on the contribution that the EU is making- towards achieving the World Summit on Sustainable Development goal for safer chemicals, namely that, by *'2020, chemicals are produced and used in ways that lead to the minimisation of significant adverse effects on human health and the environment'.*

What goal could be more important? Chemicals are essential to our way of life and they need to be produced and used so that their impact is positive – or at best, benign.

You all know that the European Union enacted the REACH regulation to try to ensure that the goal is met and created the Chemicals Agency – ten years ago, on 1 June 2007, to manage that ambition.

Let's see how far we have gone and what remains to be done.

Hitting the ground running!

The REACH Regulation was revolutionary in worldwide chemicals policy. Why? Because it required a complete change of mind-set. Before REACH, the responsibility was with the regulators to prove that a substance was dangerous – a situation that resulted in approximately 140 existing substances being regulated over 14 years. After REACH, that burden of proof is now with the companies who make chemicals. They have to register their chemicals, documenting their hazards, the likely levels of exposure and the purposes for which they are used. And companies also need to demonstrate how they can be used safely. This massive shift was a big concern to many – with companies in particular worried about capacity, workload and cost. And the evidence shows that it has not been easy, but it is being achieved, with over 11 500 companies having complied with the legislation, corresponding to over 60 000 registrations.

In recognition of the size of the challenge facing them, companies were given time to register. There were three deadlines to register substances, depending on their production volume and

toxicity. As many of you will be aware, the final registration deadline of May 2018 is fast approaching. Any companies out there that have yet to start work on their registrations, I urge them to get started now! You can find stepwise help on our website in all the languages of the EU.

In those early days, my attention was focused on getting REACH and the Agency up and running. I also wanted to establish some basic modus operandi – rooting our work in science, with independence and transparency. At the same time, we were also setting up the new Classification, Labelling and Packaging Regulation, to bring about the new globally harmonised system of classifying hazardous chemicals. Both of these Regulations set strict deadlines that had to be met, and everyone involved – industry, the Member States, the European Commission and ourselves – had to move fast in order to meet them.

In ECHA, we made important investments in IT systems to try to establish an efficient way for companies to register and to enable us to manage the massive volume of data that was coming our way. Companies have to provide up to 10,000 pieces of information on each of their substances and we needed to be able to manage it. As a result, in 2010, we received 25,000 registration dossiers for 4,300 substances. Those are big numbers! But they represent even bigger work, when you consider that the law requires companies to work together, often with their direct competitors, to make joint registrations for substances. As you recall, that requirement is there to reduce the need for duplicate testing on vertebrate animals and to save costs.

At the same time, the Classification and Labelling Inventory was set up, and over 2 million notifications for 100,000 hazardous substances were received by the legislative deadline. Even bigger numbers!

And the majority of this information was made freely available on ECHA's website. Another first.

So far, so good. But of course the role of the Chemicals Agency goes beyond receiving data and making it available. We have to evaluate the data to make sure that it complies with the law and is a sound basis for making judgements about whether substances can be used safely or not. REACH gave ECHA the target of evaluating 5% of registration dossiers and all the proposals to test substances on animals.

In this regard, those of you who follow our work closely will know that not everything in our garden is rosy. Those first years of evaluating data demonstrated that all too often, the data provided was poor. And poor data meant that the evaluation process was stopped in its tracks – it's impossible to evaluate data on a substance whose identity is not clear, with limited test results, justified on the grounds of poor quality read across from other substances.

Despite this, the process of identifying substances of concern has progressed. In the first five years, a total of 138 substances were added to the Candidate List of substances of very high concern.

Those first five years were ones of exponential growth, laying the operational foundations of our work and chasing the many challenging legal deadlines and targets set by the legislation - but also by ourselves. The European Commission also demonstrated its trust in us by asking us to take responsibility for two new pieces of legislation on Biocides and on export notifications of dangerous substances to third countries – the PIC regulation.

The second leg – working smarter

If the first five years were all about laying foundations and enabling companies to fulfil their responsibilities, then I would say that the second five years were about us working smarter. After consulting our stakeholders, regulatory partners and the public, we developed a new strategy which had four strategic objectives: getting better quality data; making sure that we use it to address chemicals of concern; resolving scientific challenges; and doing all this efficiently and effectively.

At the same time, the European Commission and Member States had developed a plan to make sure that all known substances of very high concern are identified by 2020.

So, with efficient implementation of REACH and the political commitment of the Commission and Member States, the stage was set for Europe to achieve the 2020 goal.

And yet, the fundamental pitfall was poor data. Everyone – the Commission, the Member States, stakeholders and even individual companies – knew that the data had to improve. And even more importantly, we were seeing that the data was particularly poor for the critical endpoints. I'm talking here about endpoints relating to the impact on fertility, and the ability to cause cancer and mutations.
So, we decided to change our approach. Instead of evaluating all dossiers focusing at one critical endpoint, we decided to become much more focussed on substances of potential concern.

We introduced a thorough annual screening of all the substances in our database, to identify those substances that have the greatest potential for harm to human health and the environment – we called them 'substances that matter'. This screening is a combination of IT and manual, and we do it jointly with the Member States. Our target was to identify substances that merited thorough evaluation, or even those that merited moving straight away into risk management.

To improve the screening outcome of the database we also had to make sure that the base quality of new or updated dossiers would be much higher. That is why we have developed IUCLID 6 with more fields to fill and to be IT checked for completeness which we combine since July 2016 with manual check when triggered by the IT test.

We also took another approach to try to maximise the coverage of more substances. We started to work in evaluation and risk management on groups or clusters of substances and also on particular sectors of industry. In this way, we are able to review larger numbers of substances, and at the same time able to focus on those of most concern.

The most recent progress report on evaluation and the implementation report on the SVHC roadmap are proof of the large scale action of our evaluation and risk management work where we tackle hundreds substances of potential or effective high concern to decision or opinion making.

We are still in the relatively early days of the new approaches, but we certainly believe that we are on the right track and that substances of high concern now have a much greater likelihood of being identified and addressed by 2020, while we can assure consumers that the other commonly used substances are of little or no concern.

But the 2020 goal also talks about the safer USE of chemicals. And to that end, we've made good headway with stakeholders in developing sector use maps. Together, we hope that these

harmonised use maps will ease the communication between downstream users and manufacturers on how substances are really used. I urge you to take a look at them – and maybe get some inspiration for your sectors of industry.

And the final issue that needs more effort if we are to reach the goal fully is related to consumers. The extensive database that ECHA holds on chemical substances needs to be connected to chemical mixtures and industrial articles that consumers buy. Currently, despite the specific provisions there is still very little information for consumers on articles containing the most dangerous substances, particularly those imported in mass into the EU. We should receive far more notifications of articles like these, enabling customers to buy SVHC free products and articles. My colleague Director Jack de Bruijn will moderate tomorrow morning's session which tackles this issue.

What will success in 2020 look like?

How will we know that we have reached our 2020 goal? These things are notoriously difficult to measure. With that challenge in mind, we discussed this issue last year, with our stakeholders, the Member States and the Commission. We agreed on key 'success factors' and have proposed indicators to measure success. You can find a leaflet on these at the ECHA stand. Pls have a look at these. We intend to assess success in reaching the 2020 goals on that basis. I invite other countries to do the same.

Beyond 2020

Of course, our work doesn't end in 2020. REACH continues and will play its role in achieving the goals set within the 2030 Agenda for Sustainable Development adopted at the United Nations Sustainable Development Summit on 25 September 2015.

The 2030 goals specify the need to improve water quality by minimising the release of hazardous chemicals and materials and to substantially reduce the number of deaths and illnesses caused by hazardous chemicals worldwide. They will be discussed this afternoon by another panel.

ECHA intends to play its full role in helping the EU to meet these important global goals for safer chemicals. We recognise that we cannot achieve them on our own and I pay tribute to the excellent collaboration we have had with the regulatory authorities and industry both inside and outside the EU. We would welcome further suggestions over the next two days on how to strengthen this partnership and collaborative effort even further.

Ladies and gentlemen, I wish you a productive time at this year's Helsinki Chemicals Forum and I look forward to the lively discussions over the coming two days and to the conclusions, for which my Deputy Jukka Malm will make daily concluding remarks.

Annex: success factors in the meeting with WSSD 2020 goals

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ECHA
EUROPEAN CHEMICALS AGENCY

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Success factors in meeting the WSSD 2020 goals

1) Robust data is available on all chemicals in Europe

a) All chemicals critical for the supply chain in Europe are registered without unnecessary market disruption.
b) Companies see the data on their chemicals as their business card and are committed to keep their registration dossiers up-to-date with new relevant information.
c) Registration dossiers are compliant and contain the data covering the hazards and uses of substances adequately. This allows them to be adequately classified, labelled and used safely. Companies can use the information for substituting hazardous substances, and by that spur innovation.
d) Hazard data is generated using non-animal testing methods and new approaches wherever possible.
e) ECHA has concluded, preferably in co-operation with the relevant stakeholders, which high-volume substances (above 100 tonnes per year):
    i. Are of concern;
    ii. Are currently not of concern; or
    iii. Need more data for a judgement to be made.
f) A plan describes how ECHA will identify candidates for further evaluation and/or risk reduction amongst the lower volume substances (1-100 tonnes per year).
g) Divergence in industry self-classification has decreased significantly.

Measures for implementation	
1.	ECHA together with its partners and stakeholders ensures that all actions identified in the 2018 roadmap are carried out as planned.
2.	ECHA concludes by 2020 well over 1000 comprehensive compliance checks for substances of potential concern in the 100-1000 and >1000 tonnes tonnage bands.
3.	By 2020, Member State competent authorities (MSCAs) evaluate over 400 priority substances under substance evaluation and ECHA requests necessary data to conclude on suspected risk. MSCAs conclude the evaluations when the data is available and identify the most appropriate risk management measure.
4.	To increase the quality of registration dossiers, ECHA and Member States carry out joint evaluation efforts with a considerable number of volunteering sectors of industry. In addition, ECHA also undertakes where useful targeted campaigns for specific types of registration and other complementary measures.
5.	ECHA adapts its registration and data sharing processes to prevent that companies submit incomplete dossiers and to prevent the use of these processes for other purposes than they were intended for (e.g. distortion of market). Where appropriate ECHA challenges early registrants who have not shared data or whose dossiers are incomplete based on the updated completeness check rules. Any inaction or insufficient action will trigger revocation.
6.	ECHA has screened with IT-tools the substances with registrations only in 1-10 tonnes and 10-100 tonnes tonnage bands. A plan is in place for compliance check or substance evaluation for 2020-2025 and to support the decision whether >100 tonnes dossiers should be prioritised.
7.	Registrants implement the revised information requirements for nanomaterials, and ECHA reinforces them via updated guidance, advice, compliance checks and complementary measures.

8.	Registrants document their considerations on alternative methods and approaches with adequate justifications why these are not sufficient to meet the relevant information requirement before proposing new animal tests in their registration dossiers.
9.	To further reduce the need for animal testing ECHA promotes the use of new alternative methods and approaches developed in the EU and internationally via guidance, advice, awareness raising and training. Where relevant, the Commission is updating the information requirements without undue delay.
10.	In the event the CLP Regulation is not revised to oblige notifiers and registrants to share data and to resolve any unjustified differences in their self-classifications, a considerable number of notifiers and registrants have been challenged to sort out their differences in classification or face proposals for harmonised classification triggering also spontaneous updates by others.

2) Effective regulatory risk management of the most dangerous chemicals takes place

h) Substances of concern are identified, either individually or in groups. The most appropriate regulatory risk management measure to protect health or the environment, either under REACH and CLP or other legislation has been initiated.

i) The processes for authorisation, restrictions, and harmonised classification and labelling are fully optimised and operate based on fit-for-purpose dossiers. They allow efficient opinion-forming in the committees and swift decision-making by the Commission.

Measures for implementation	
11.	ECHA communicates effectively to MSCAs and the Commission about substances that need regulatory risk management. This happens mainly through the SVHC roadmap activities and risk management expert meetings. Resulting proposals for CLH, SVHC, authorisation or restriction are developed within a reasonable timeframe.
12.	Substitution of the most dangerous substances is effectively promoted by having all relevant currently known SVHCs in the candidate list by 2020. ECHA regularly recommends substances for inclusion into the Authorisation list and the Commission regularly adds substances to this list whilst taking account of the resource implications.
13.	The restrictions and applications of authorisation processes are reviewed and improved to render them more affordable, workable and predictable.
14.	The Commission puts forward a series of legislative and non-legislative proposals to make better use of the data generated for REACH and CLP and support the development of risk reduction measures under other legislation.

3) Effective communication takes place about the safe use of chemicals up and down the supply chain

j) Information about substances flows effectively up and down the supply chain. Companies that use chemicals inform their suppliers about what they do, and in return, manufacturers and importers provide information on how to use them safely.

k) Importers and EU producers of articles have improved their knowledge on the substances present in their articles to provide adequate safe use advice to their

customers and promote substitution.

Measures for implementation	
15.	ECHA, Member States, and industry associations support registrants and downstream users to adopt the methods, tools and standardised formats (such as use maps) developed under the chemical safety assessment roadmap. Registrants and companies further in the supply chain use these tools widely.
16.	ECHA promotes the communication among industry and between industry and authorities on implementing exposure scenarios as a novel communication vehicle. It also serves different EU environmental and health legislation.
17.	ECHA, the MSCAs, the Commission, sector organisations and NGOs jointly carry out further awareness-raising among importers and producers of articles on their obligations related to substances in articles and increase the cooperation with third countries to identify, and where needed, take action (e.g. at international level) on substances of high concern.
18.	A fundamental review of the legal requirements for information on substances in articles is carried out. This could usefully form part of work on the circular economy and the drive towards a non-toxic environment.

4) A step-change for citizens, businesses and the regulators takes place

l) Information on chemicals is reliable, understandable, freely available, and easy to use. This allows citizens, stakeholders, businesses and regulators to make informed choices on using and substituting hazardous substances, and to increase their confidence in the safety of chemicals – not just in Europe, but around the world.

m) The experience of REACH and CLP, the information, methods and tools developed are increasingly recognised and used worldwide.

n) Companies experience firm, fair and harmonised enforcement, focussing on ensuring the safe use of hazardous chemicals and fostering a level playing field.

Measures for implementation	
19.	ECHA is a data hub for safety information on chemicals. ECHA expands this central data management and dissemination role by exploring integration and synergies with other EU legislation after 2018.
20.	ECHA and Member States promote the development and use of common and harmonised methodologies and tools at OECD and other international fora.
21.	ECHA promotes the availability and use of the information on chemicals safety to third countries and to stakeholders outside of the EU to assist them in their efforts to improve their chemicals management systems.
22.	Member States implement effective and harmonised enforcement to foster a level playing field and safe use of substances. All MS's participate in this activity, and ECHA facilitates it via the Forum.