summary on chemical lobbying

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Chemical Lobbying

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Section 1 – Road Maps on Substance Regulation

16th February 2023
Uncategorised

Procedures for Regulating Substances in one easy table

25th May 2020
Comitology

There are over 40 pieces of EU legislation dealing with chemical substances.

The legislation is managed by different Commission departments (ENV, GROW, SANTE, Employment), and different agencies (ECHA, EFSA).

The procedures substances go through vary. Most go through secondary legislation – either delegated acts, implementing acts, and many still go through the regulatory procedure with scrutiny (RPS).

Below is a summary of some.

Procedures

Regulation	Procedure
REACH Restriction	RPS
REACH Authorisation	Implementing act
REACH SHVC identification	Implementing act
REACH Test Methods	RPS
CLP Classification ATP	Delegated act
RoHS substance restrictions	Delegated act
RoHS exemptions	Delegated act
Endocrine Disruptors Criteria – Plant Protection Products	RPS
Endocrine Disruptors Criteria – Biocidal Products	Delegated act
GMO Authorisation	Implementing act
Plant Protection – Maximum residue levels (MRLs)	RPS
Plant Protection Products – Renewals	Implementing act
Plant Protection Products – Approval	Implementing act
Toys migration limits	RPS
Toys – harmonised standards	RPS
Foodstuffs – maximum levels for certain contaminants	RPS
Foodstuffs – maximum levels for certain contaminants	RPS
Ecodesign	RPS
Ecolabel	RPS
POP Annex I update	Delegated act
Biocides – national restrictions	Implementing act
Medical product for human use – authourisation	Implementing act
Occupational exposure to carcinogens and mutagens – CMD – Binding OELs	Ordinary legislation – special procedure
Indicative occupational exposure limit values – CAD	Delegated act

Find the right map – dealing with chemical law making

9th December 2018
Comitology,EU

As a lobbyist your job is going to be full of variety.

Given that variety, it helps to have the right 'map' to guide you through your journey.

EU law making is not fast. It is full of opportunities to intervene and make your case.

During your journey, you'll need a detailed paper or electronic road map.

Sometimes, you are going to need country and city specific maps.

You'll need to make sure that the map that you are using is up to date.

Today, you can use GPS. Sometimes it is up to date, but it may not tell you when a motorway is out of action.

Maps are not usually transferable

Today, I spend a lot of time on chemical legislation and policy. . I deal a lot with substances being added to the CLP's Annex and REACH.

With time, you get to learn the process, steps, and issues you can and can't raise. You get to understand the map and best routes to take and as importantly avoid.

Yet, I have worked in other areas, like fisheries, where the map is totally different.

Lobbyists working in fiance use a very different map.

For me, there would be no point in blindly re-using the map I used in fisheries in chemicals. I'd at best get lost very quickly, and more likely far worse.

I like case studies. It is the inner lawyer lurking in me. You can learn a lot looking at the precedents. No all cases go the same, and exceptions happen. Yet, the case below, provides a good example of the usual process and timescale for updating the ATP.

The case here is the 10th ATP. I choose this for no better reason than it was tabled and adopted under this Commission.

To date, no CLP ATP updates have gone through the 'Better Regulation' 4 week public consultation. There is no evidence of the 10th ATP going through the Better Regulation public consultation. My own view is that they should.

Unfortunately, in the case study below, the dates for inter-service consultation for the adoption of the proposal are not listed. The Commission keep this part of the process, arguably the most important, away from public view.

Key Dates

1. CARACAL – list of substances for possible inclusion for which the European Chemicals Agency (ECHA) has adopted opinion in 2015 (or earlier) was circulated for feedback and comments to by 8 April 2016	***24 February 2016***
2. CARACAL informed of 10th ATP	***23 March 2016***
3. REACH Regulatory Committee informal discussion on 10th ATP	**7 July 2016**
4. Commission submits Draft Measure to WTO	***15 September 2016***
5. WTO Consultation on 10th ATP closed	***21 October 2016***
6. Member State experts (REACH Regulatory Committee) approve update to ATP 26 Member States in favour, 2 against	***26 October 2016***
7. Commission ask delegations to express objections possible opposition to draft measure	***11 November 2016***
8. Deadline for delegations to express possible opposition to draft measure	***12 December 2016***
9. No objection Permanent Representatives Committee (COREPER)	***13 January 2017***
10. Council confirm (link) no objection	***23 January 2017***
11. Deadline for EP & Council to object EP & Council no objection	***10 February 2017***
12. Adopted 5 May 2017 – Commission Regulation (EU) 2017/776	***5 May 2017***
13. Entry into Force	***25 May 2017***
14. Apply from	***1 December 2018***

Some reflections on dealing with substance classifications (print material)

16th February 2023
Case Studies

Having done a few substance classifications (CLP), I get a few questions about the Commission and the Member States view the process. I have pulled together my notes and put down how the Commission and most Member States see the process.

I think it is key to understand how the people informing and making decisions see things. After all, if people saw things from your perspective, it is unlikely your substance would be looked at.

I have tidied up my scribbles below as a checklist.

1. You need to provide your science when the RAC is considering the file.
2. If you provide science after the RAC has given an opinion, the best way to re-open the file is to get a Member State to submit a new classification. There are a limited number of cases where the ECHA Executive Director re-open the file (see link).
3. Officials (Commission and Member State) are reluctant to second guess the RAC.
4. Officials don't like engaging on chemical substance; they are considered too sensitive.
5. The final outcome of the RAC will most of the most be co-opted in the ATP update.
6. Harmonised classification under CLP is about hazard classification. Risk management is not an issue.
7. The RAC's view is seen as more thorough than industry's self-classification.
8. The main first-order consequence of classification is common labelling and packaging.
9. This help provide information to the users when using the substance
10. There may be second-order impacts when classification triggers risk management in other legislation
11. You can see the list of substances classified in Annex VI (link).
12. The Commission considers they have a legal requirement to automatically transcribe the new opinions into the Annex; they contend they have no discretion. They follow this in most cases.
13. The Commission and the Member States will consider constructive suggestions to effectively translate the RAC opinion to Annex VI
14. The RAC does not rubber-stamp Member State classification dossiers.
15. ECHA transmits a consolidated list of RAC opinions at the start of the year. It's in the same format as the ATP.
16. The Commission discusses the draft adaptation to technical and scientific progress (ATP) with the expert group – CARACAL.
17. The Commission then develop the draft legal text.
18. The Commission consults with the WTO.
19. After the feedback, the Commission adopts the delegated act.
20. If you review the notes, you will see some moves to make the classification more operational.
21. Member States sometimes use the classification process as a means to get more information about a substance.
22. Even if other legislation may address any identified risks, the Commission and most Member States believe that the CLP is the appropriate regulatory instrument.
23. Socio-economic factors are seen as non-issues.
24. The Commission does not consider there is the need for an automatic impact assessment for a classification.
25. Some in the Commission question the need for a Better Regulation public consultation for a CLP update (rerun of ECHA consultation) (link)
26. Second-order impacts can only be considered under other pieces of legislation.
27. The Commission may, from time to time, undertake an assessment of the impacts of a classification.
28. A category 2 classification has limited if any direct impacts.
29. Some legislation permits the use of category 2 granting of authorisation, exemption, demonstration of safe use.
30. Ongoing procedures like substance evaluation do not detract from going ahead with the ATP listing.
31. Some Member States use the CLP as a gateway to regulatory follow-up action.

A few personal observations:

1. The key window of opportunity is the deliberations of the RAC and their final opinion.
2. The best way to engage is with a significant and long-established body of world-class science on all substance endpoints. As a rule of thumb, I take ten years as the minimum level.
3. Coming in late or not at all is unlikely going to work out well.
4. Saying you are right and the RAC is wrong are phrases that to fall on deaf ears.
5. The burden of bringing new science to the table to re-open a RAC opinion is very high.

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A flight plan for a REACH Restriction

7th July 2019
Case Studies

A flight plan for a REACH Restriction

Poland tabled a proposal to restrict methanol in windscreen washing fluid. There was a spate of people drinking the windscreen washing fluid thinking it contained alcohol. They were poisoned.

Observations

Putting forward a REACH Restriction is a time-consuming and resource-intensive process. It's obviously not embarked on lightly

There are time limits for the ECHA stage, but slippage seems a constant during the Commission's adoption.

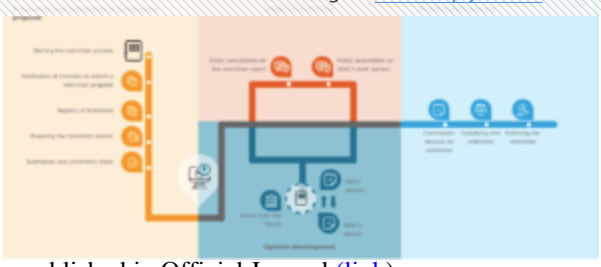
After the submission, the review by RAC and SEAC raised important questions that led to revisions. A group of SEAC members appeared at best circumspect about the merits of the submission. China raised reservations during the WTO consultation.

The REACH Committee was divided. 19 voted in favour, 8 against, and there was 1 abstention. Despite this, there was no challenge by the Council or the European Parliament.

A Case Study: Methanol REACH Restriction

Procedure: RPS

1. 2012: Poland starts work on Substance Evaluation
2. 17 September 2015: Poland Substance Evaluation Report on Methanol concluded, recommends restriction
3. 19 December 2013: Notification by Poland to ECHA of intention to submit a Restriction proposal
4. 1 August 2014: Poland submits a dossier to ECHA
5. Conformity check by ECHA
6. ECHA notify Poland that the dossier is not in compliance with an Annex XV dossier
7. Poland notification of intention to re-submit
8. 16 January 2015: Poland re-submit dossier to ECHA (link)
9. Start Scrutiny by ECHA Committees
10. 18 March 2015: ECHA launches public consultation on the proposal (6 months – ends 18 September 2015)
11. 17 September 2015: ECHA public consultation deadline ends
12. 12-13 November 2015: CARACAL updated on progress
13. 4 December 2015: SEAC draft opinion adopted
14. 4 December 2015: RAC Opinion adopted
15. 9 December 2015: Press release of the adoption of the RAC Opinion
16. 9 December 2015: SEAC draft opinion launch for public consultation
17. 9 February 2016: Deadline for public consultation on SEAC draft opinion
18. ECHA transmit opinions to Commission
19. Commission prepare an amendment to restrict methanol
20. 8-9 March 2016: CARACAL members receive an update on restriction
21. 29 June – 1 July 2016: CARACAL members receive an update on restriction
22. 7 October 2016: Commission notifies WTO of draft restriction
23. 5 December 2016: Deadline for WTO consultation closes. China makes submissions.
24. 16 February 2017: REACH Committee exchange of views on the revised proposal
25. 24-26 October 2017: REACH Committee (Member State Committee) adopts draft measure (19 in favour, 8 against, 1 abstention) (link to voting results)
26. File transmitted to European Parliament and Council
27. 14 December 2017: Council working group raises no objections
28. 10 January 2018: COREPER raise no objections
29. 23 January 2018: Council (Economic and Financial Affairs Council) raise no objection
30. 10 February 2018: Deadline for objections – No objections raised

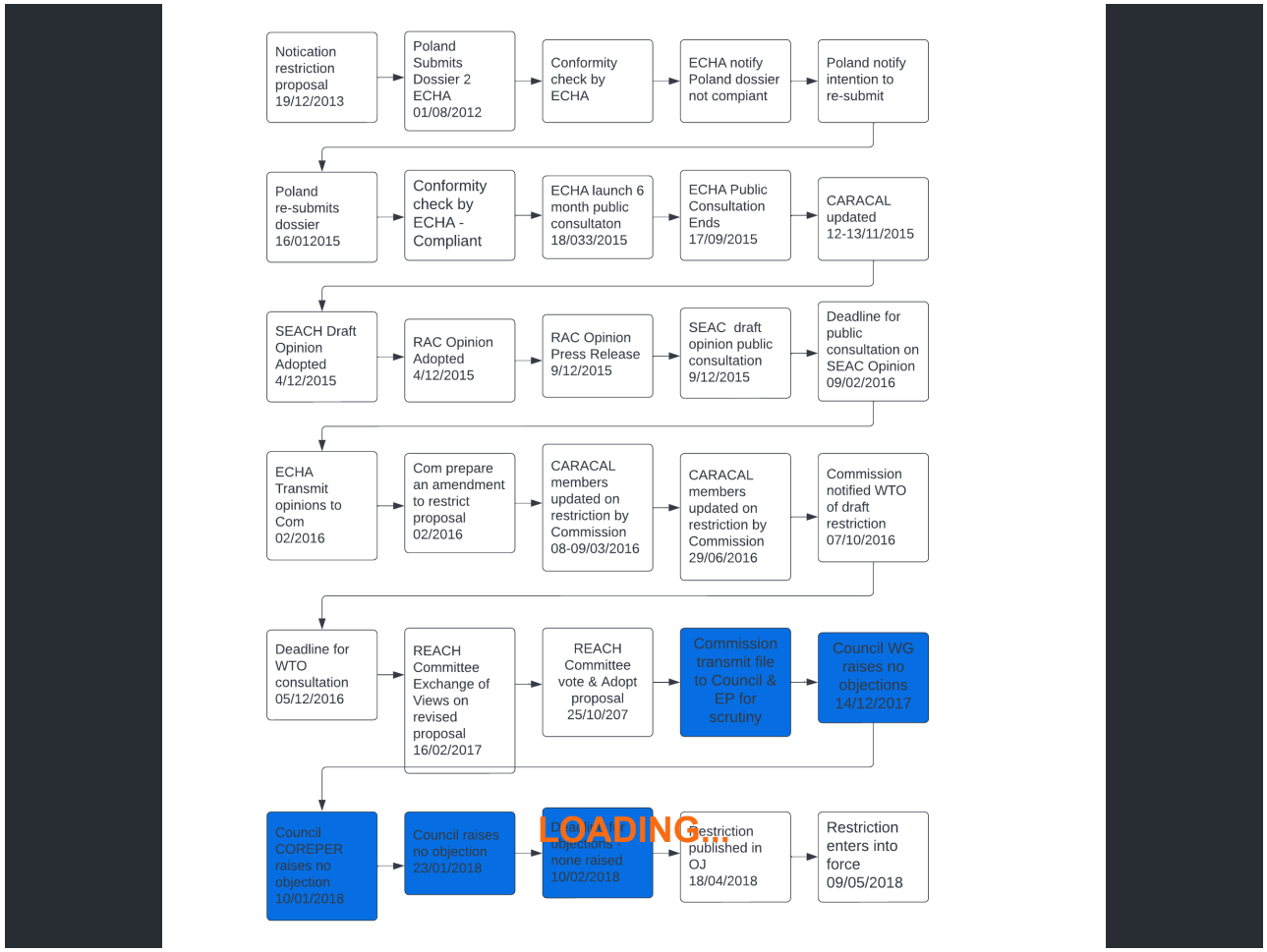


31. 18 April 2018: Restriction published in Official Journal (link)
32. 9 May 2018: Restriction enters into force

Process Charts

ECHA's process chart is good. You can find it here and below.

Or there is a less colorful version.



Blue is the political scrutiny phase.

Lessons Learned

There are many opportunities to make your case in the REACH Restriction process. Here are some personal observations dealing with the REACH Restriction process.

1. You usually have a lot of pre-warning that something is in the works. This gives you the time to prepare a robust technical and scientific case for when the proposal comes.
2. You should go and speak with the Member State who is looking into your substance. The smart play is to assist that Member State find the answer to the questions they are after. After all, they have the real power in this process.
3. If you stall and take other steps to infuriate them, you can't be surprised when they scratch back. Pissing a government off is never a smart play in the short, medium or long term. Pissing them off when they have a lot of flexibility is plain silly. So, don't do it.
4. Work with the country to solve the perceived problem. If they think you need tighter product or workplace emission standards, do everything you can to get those measures in place.
5. Make sure that your dossier and safety sheet is in order. Fix any gaps. If the consortium does not want to spend another 15 euro to make things better you have only yourselves to blame.
6. Make sure that you have a world-class submission ready to go. I've found peer review from hell from an objective and independent third party well experienced in the particular regulatory process helpful. It will only strengthen your case, and allow any weak points to be improved or removed outside the public glare.
7. Ideally you'll do this before the actual drafting of the proposal starts and the latest before the scrutiny by ECHA starts'. The later you bring in new evidence the bigger the chance it will be omitted. If you generate new evidence during the process, it has to be world class and ground breaking if you want to be it considered. Calling to stop the process because new studies are ongoing and one must wait for new data to be available, has never worked.
8. In practice, your best defense is to have a long term science programme independently looking at each and any problem that may be there. This allows you to have the best and most up to date evidence ready when governments come knocking to look into your substance.
9. Turn up to the many chances you have to make your case. And, when you do so, try some humility. People tend to like likeable people.
10. Have your case written down in different versions for the technical, scientific, and political audiences you are going to deal with. Using the same script for all audiences does not work.
11. Some windows of opportunity are more useful than others. The Public Consultation, attending RAC/SEAC, speaking with Member States for CARACAL, and the Commission are the best. The real key is making an early and strong written submission in the pubic consultations.
12. The public consultation has 2 deadlines: the first one typically ends 1-2 months after the launch of the consultation. It's not a hard deadline, but any info you want to be considered by RAC from the beginning, this is when your evidence must be submitted. If you only submit info by the end of the 6-month deadline you risk that RAC has already taking a decision on some parts like the hazard assessment and it's very hard to reopen discussions.
13. Most decisions are taken by written procedure, so people need to rely on strong written submissions that make the point clearly and with real and robust evidence. Statements of faith without strong data and evidence are pointless for CLP and REACH processes.
14. I am circumspect that the WTO notification process offers any real chance of changing direction. A lot of people will disagree with me. I've just never seen it work and that's a view those closer to the files confirm. Personally, I've seen objections from the USA, China and India hardens support for a proposal both for regulatory and ordinary legislative proposals.
15. After the technical adoption, there is limited leeway inside the Commission. On Restrictions, the Commission is more prone to exercise their discretion, than say for classifications.
16. Their margin of maneuver is greater around procedural errors.
17. Officials in the Commission and Member States are loathed to second guess designated scientific experts (RAC) on chemical issues. It makes them very nervous.
18. The REACH Committee seems to always back the Commission. Sometimes there are small groups of Member States who vote against the proposals for various reasons (too weak a proposal or too strong) but not enough to risk the Commission's proposal not being carried.
19. When the draft proposal is sent to the Council and EP for scrutiny (because Restrictions are RPS measures), there is a limited window to have things changed. The challenge is likely to come from the EP. This has happened and because it is a RPS measure, the measure falls.
20. If you want to reach out to the Member States or the EP, it helps to have existing relationships, be trusted, and have a compelling technical, scientific and public policy case to support you. Highlighting the bigger picture helps. The chances of success are nearly theoretical for industry backed challenges. None have succeeded.
21. If you opt for a style of sending passive aggressive letters to officials and politicians, don't be surprised when they lead to support for the proposal increasing.
22. The best way forward is to make sure the conditions that lead to governments/Commission wanting to start work on a Restriction don't happen. Once they start, it is hard to get out.

A road map for the adoption of OLP

1st July 2019
Uncategorized

From time to time, you'll need to deal with with an ordinary legislative proposal.

The process chart below outlines the steps in the journey for the adoption of the proposal.

A flight plan for a delegated act

20th June 2019
Lobbying

I am drafting some short case studies on the steps of the journey a piece of legislation goes through from beginning to end. It's useful to have a good map of the journey.

This example looks at the exemptions given under the RoHS Directive. It's a piece of legislation I know well. It's an example of a regular delegated act, where there was no challenge. Later on, I'll give those examples.

First, you'll see this process is not fast. It took four years from submission to official confirmation. if you add in the time to prepare the technical case for the continued exemption – exemptions are the exception and not the rule after all – it's about five years of work.

Second, there are a number of steps you need to walk before you get to where you want to be. If you misstep, by keeping your eye off the ball, or providing the incorrect information early on, you are unlikely to get to the end of the journey.

Third, you cross different terrains. First, you deal with a technical and data-heavy review at the beginning, which then moves into a process review, and finally political oversight. You need to be able to deal with all the terrains.

Finally, you'll see that Member States' expert groups can support the Commission through both face to face meetings and through written procedures.

A Case Study

Commission Delegated Directive (EU) 2019/171 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium and its compounds in electrical contacts

1. 8 June 2011: Directive 2011/65/EU, RoHS
2. 29 December 2014: Oeko-Institut Study starts
3. 21 January 2015: 2 applications for renewal of exemption
4. 15 July 2015: New Delegated Act Planned
5. 21 August 2015 – 16 October 2015: 8-week public consultation (link)
6. 25 August 2015: Commission launch technical study to evaluate exemption requests
7. 7 June 2016: Oeko-Institut Study Published (link)
8. 27 April until 18 May 2017: Written Procedure feedback from Member States' Expert Group
9. 15 February 2018: Public Feedback Start (link)– 3 submissions
10. 20 February 2018: WTO WBT Notification opens
11. 15 March 2018: Public Feedback ends
12. 21 April 2018: WTO WBT Notification closes
13. 16 November 2018: Delegated Act adopted (link)
14. 16 November 2018: EP deadline for lodging objections from date of receipt (link)
15. 19 November 2019: 2 month Scrutiny Period Starts for Council (date of notification) (link)
16. 17 December 2018: CORPRER – support intention not to raise objections (link)
17. 8 January 2018: General Affairs Council- Confirm Intention not to raise objections (link)
18. 16 January 2019: 2-month deadline for European Parliament lodging objections ends
19. 19 January 2019: Deadline for EP to object ends
20. 21 January 2019: Deadline for Council to object ends
21. 05 February 2019: Publication in Official Journal
22. 25 February 2019: Entered into force

A flight plan for ATP

23rd June 2019
Case Studies,Comitology,Lobbying

A chemical lobbyist will spend a lot of their time dealing with updates to the ATP.

I've taken the timeline for one substance – Formaldehyde – that was part of the 6thATP.

I've detailed the long journey as I think it is a good case study for these reasons:

First, it is a regular classification update. The schedule and transposition of the RAC's file are like this for 99% of classifications.

Second, you'll see that a lot of the process, both scientific and legislative adoption, is done by way of written procedure. If you think everything is done in face to face Committee meetings, you are living in the pre-internet era. The adoption of decisions by way written procedure is normal.

Third, for most cases, there is little to no interest in challenging the opinion of the RAC from the Commission, EP, or the Member States.

Note:

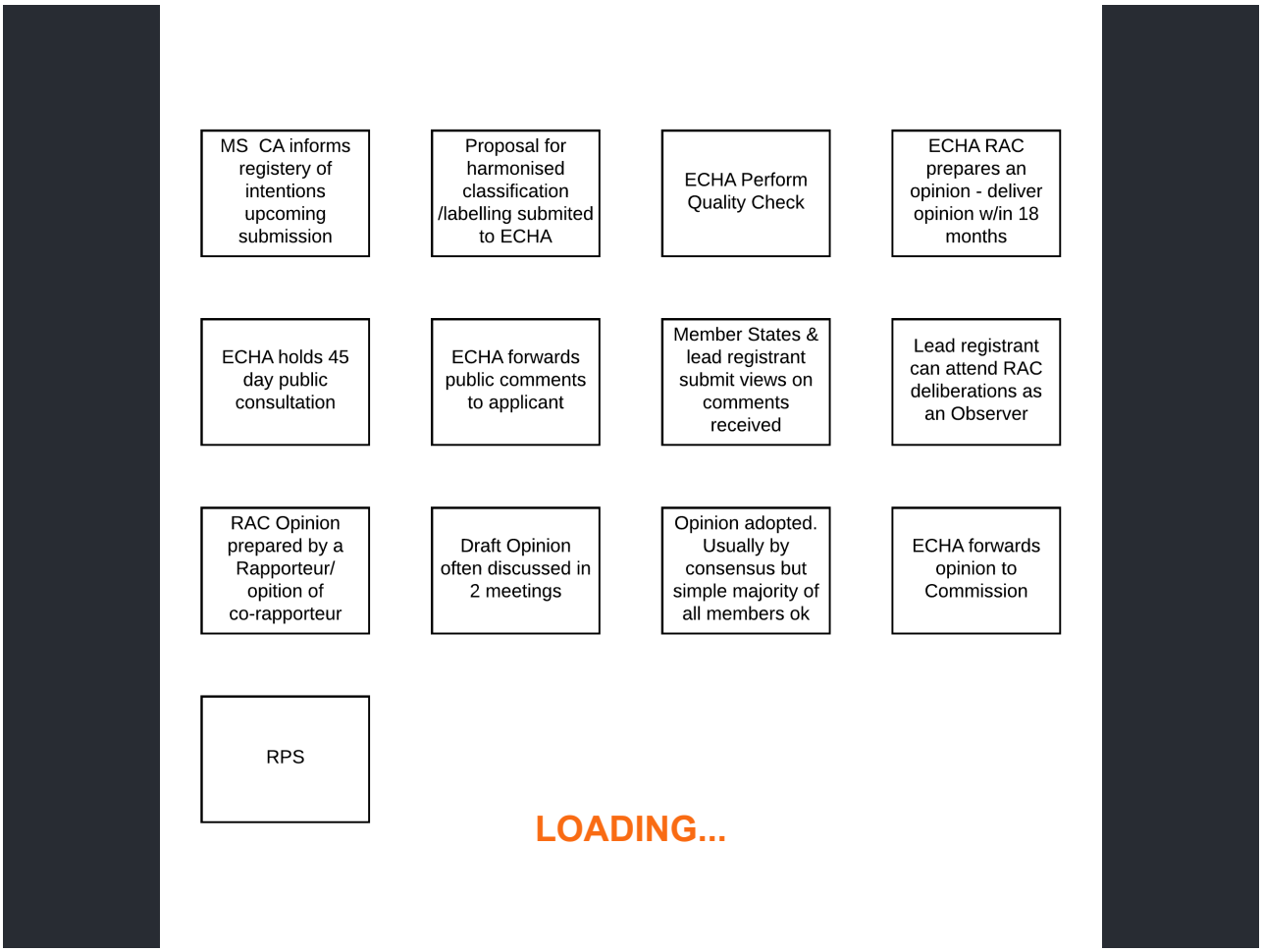
1. all the steps below are on the public record.
2. Not all the exact dates can be sourced.
3. The ATP was adopted by way of Regulatory Procedure with Scrutiny. In July 2019 it will become a Delegated Act.

Updating classifications – the 6thATP & Formaldehyde

1. 4 March 2011: REACH Registration Dossier published
2. 10 June 2008: Registration of CLH intention by France
3. 30 September 2010: Dossier submitted by France to RAC for accordance check
4. 28 September 2011: Final submission by France – proposal Carc. IA
5. 30 March 2013: Deadline for the adoption of an opinion
6. 31 October 2011: Start of public consultation
7. 15 December 2011: Deadline for comments
8. 11-14 September 2012: Discussion in RAC of first draft opinion (link)
9. 30 November 2012: 2ndiscussion on draft opinion and adoption of RAC Opinion (link)(link)
10. RAC Opinion by a simple majority. One minority opinion (link)
11. 7 December 2012: RAC adopts opinions (link)
12. 29 April 2013: Legal deadline for Opinion
13. Q1 2013: ECHA transmit updated classification to European Commission
14. Q1 2013: Draft Submitted for Inter-Service Consultation (Services)
15. Note: Now a 4 week Public Consultation of Draft for public consultation
16. 21 February 2013: REACH Committee discuss ATP
17. 1 March 2013: Commission submits draft 6thATP
18. 13-14 March 2013: CARACAL discusses draft ATP.
19. 18 March 2013: Deadline for written comments from CARACAL
20. March last week: Inter-Service Consultation
21. 19 June 2013: REACH Committee discuss draft ATP. No vote.
22. November 2013: CARACAL discusses draft ATP.
23. 11 November 2013: Written procedure launched
24. 2 December 2013: COM suspend written procedure of 11 November. Vote on 17/12/13

25. 3 December 2013: Deadline for written procedure
26. 17 December 2013: Vote in REACH Regulatory Committee – approves
27. 15 January 2014: Draft measure transmitted to Council and EP for scrutiny – 3 months (link)
28. 14 April 2014: Deadline for Council and EP to raise objections. None raised.
29. 6 June 2014: Commission Regulation published in Official Journal (link)
30. 26 June 2014: Entered into force

A process chart for the CLP's ATP



Why lobbyists need a flight plan – a case study

19th June 2019
Lobbying

Pilots have flight plans. Before they go into the air , they go through a checklist and review their flight plan. When they are in the air, they'll adjust their journey, depending on weather conditions and turbulence. Their final journey won't be exactly the same one they planned for. They know from the start that they'll make adjustments during the journey.

A good pilot knows that if they just jumped in and took off without a journey plan, the chances of landing safely, if at all, are slim.

When you prepare for the journey, you see how long it is going to be, and what you need to bring along. If you don't know the journey, you may be caught out, and think the journey is a short one, but then forced to land or crash in the sea when you discover it is a lot longer than you had planned for.

When embarking on a legislative or policy file, I find it useful to know the journey's map. I've taken to looking at similar journeys taken by others to get a good idea of the map. It helps see what preparations are needed, and if possible, improve on the journey plan. I know from the start that adjustments will be needed during the journey. The voyage won't be smooth.

Case Study

A case study is the adoption of occupational exposure legislation.

In 2016, the Commission started the process to amend Directive 2004/37 on the protection of workers from the risk related to exposure to carcinogens or mutagens at work.

Below, I have chunked down the key steps by date.

It could as well be represented by a process chart and a journal record of the legislative journey.

What you'll notice from it, is that the voyage is not a short one – more than 3 years. There are several important steps in the journey, from political validation, scientific deliberation, review by the social partners (which is unique to OELs), the adoption by the Commission, and legislative adoption by the Council and the European Parliament.

The journey is broken down into several important chunks or steps. If you miss one important step, you're likely to land up in the wrong place, or in the right place at the wrong time, or simply crash.

Stages in the Journey

1. Commissioner Marianne Thyssen backs 3rd CMD – 23 May 2016
2. SCOEL informed of new list of substances to be evaluated – 12 September 2016
3. SCOEL Recommendation adopted by SCOEL – 30 June 2016 [8 hour 0.3 ppm]
4. Working Party on Chemicals (WPC) (a sub group of ACSH) – 15-16 June 2016
5. Advisory Committee on Safety and Health at Work(ACSH) – 9 September 2016 (link)
6. SCOEL Recommendation on Formaldehyde published – 6 March 2017 (link)
7. Joint Declaration of on the EU's legislative priorities for 2017-2018 – 14 December 2017 (link)
8. Road Map launched Public 4 week feedback opens – 27 November 2017 (link)
9. Road Map Public feedback closes 4 submissions – 25 December 2017 (link)
10. Draft impact assessment report submitted to the RSB – 30 January 2018 (link)
11. Regulatory Scrutiny Board positive opinion – 23 February 2018
12. Regulatory Scrutiny Board opinion with changes incorporated – 30 January 2018 (link).
13. Services Draft proposal – February 2018
14. Inter-Service Consultation – March 2018
15. Commission proposal adopted – 5 April 2018 (link) (Press Release link)
16. Post proposal feedback opens – 5 April 2018
17. Post proposal feedback closes – 4 June 2018

18. European Parliament Employment and Social Affairs Committee draft report – 29 June 2018 (link)
19. Economic and Social Committee Opinion – 19 September 2018 (link)
20. Amendments tabled in committee 24 September 2018 (link)
21. Vote in Committee – 20 November 2018 (link)
22. Committee decision to open inter-institutional negotiations with report – 20 November 2018 (link)
23. Committee report tabled for plenary, 1st reading/single reading – 23 November 2018 (link)
24. Coreper letter confirming inter-institutional agreement 15/02/2019 (link)
25. Approval in committee of the text agreed at 1st reading inter-institutional negotiations – 19 February 2019 (link)
26. Text adopted by Parliament, 1st reading/single reading – 27 March 2019 (link)
27. COREPER agree – 15 May 2019
28. General Affairs Council adopt – 21 May 2019 (link)
29. Final Act – 5 June 2019 (link)
30. Next Steps – publish in Official Journal

A new road map for CLP ATP – the shift to delegated acts

30th June 2019
Uncategorized

The updates of the CLP's ATP will soon shift from RPS to Delegated Acts. REACH will still sit under RPS and be supported by the REACH Committee. CARACAL will become the 'Expert Group' dealing with delegated acts.

The Commission submitted proposal a proposal to manage the transition on 28 June 2019.

I've tried to put it into a process chart (see below).

For ongoing files, in particular, the 14th ATP, a follow-up consultation of the expert group will happen.

On 18 July 2019, documents will be transmitted to the European Parliament after the end of the recess period.

The new regime will enter into force on 26 July 2019.

You can track the adoption of delegated acts via this useful link.

Points of contention

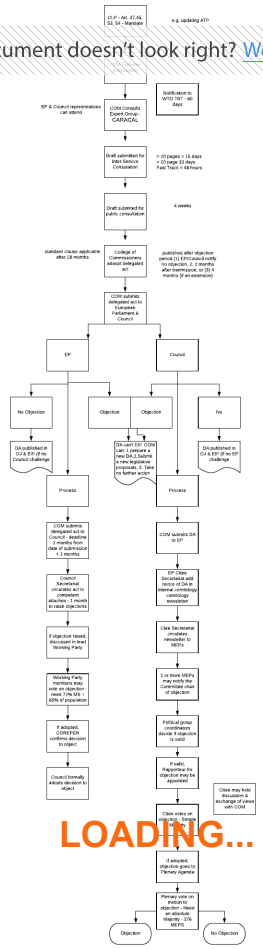
The Commission notes "Under the delegated acts procedure, the Commission's preparation of draft texts under CLP will continue as before. They will be subject to publication by the Commission under the public feedback mechanism (unless they concern harmonised classification and labelling, as the public consultation takes place at the level of ECHA). They will also be discussed with Member States and stakeholders at the CARACAL meeting" (page 4).

This seems to be at odds with their current practice. For the 14th ATP, the Commission launched a public consultation (link) on 1 1 January 2019 that closed on 8 February 2019. It received 489 submissions.

The reason for this change is that on draft implementing acts, there is a 4-week feedback period.

If an Agency has already done this and the Commission is simply following the recommendations of the Agency, then the COM does not have to repeat the 4-week feedback.

The same applies to draft delegated acts. For delegated acts, the lead Directorate-General must discuss the draft legal text with other Directorate-Generals before the adoption by the College.



Does the Commission have to follow the scientific advice?

6th November 2019
Better Regulation

Do the Commission exercise their discretion under Article 37(5) CLP

The Commission has the inherent flexibility and the flexibility provided by the CLP Regulation how they incorporate RAC opinions into the ATP.

Article 37(5) of CLP (link)

Article 37(5) of the CLP spells out how the Commission are meant to take forward the incorporate new RAC opinions.

"The Commission shall without undue delay adopt delegated acts in accordance with Article 53a, where it finds that the harmonisation of the classification and labelling of the substance concerned is appropriate, to amend Annex VI by inclusion of that substance together with the relevant classification and labelling elements in Table 3.1 of Part 3 of Annex VI and, **where appropriate**, the specific concentration limits or M-factors. A corresponding entry shall be included in Table 3.2 of Part 3 of Annex VI subject to the same conditions, until 31 May 2015. Where, in the case of harmonisation of classification and labelling of substances, imperative grounds of urgency so require, the procedure provided for in Article 53b shall apply to delegated acts adopted pursuant to this paragraph" (emphasis added).

It is a discretion that the Commission use rarely exercise. Some deny that the discretion exists.

A recent case shows that the Commission does, although rarely, exercise their discretion.

Second Order Impacts

If the Commission can and do exercise this discretion it invokes second order impacts.

As a working rule the Commission have turned down requests to run impact assessments on classification proposals.

Their reasoning is that they have no discretion and their guidance provides them the margin of manouvre wheen they have discretion.

"1. An impact assessment will be necessary where there are likely to be **significant impacts** and where the **Commission has discretion** about the measures which could be taken (including whether to act at all). For example, a scientific body may recommend a safe exposure level to a particular chemical but the Commission has the choice of how best to manage the risks of exposure to that chemical'.

The Commission can't pick and choose. If they decide in one case they have the discretiont to take forward a scientific body's opinion, surely that discretion is open for all. To treat similar cases differently is poor governance.

Case Study – DTPA

In the case pentapotassium (DTPA) (CAS Number: 7216-95-7/ EC Number: EC Number: 404-290-3) the RAC's Opinion of 9 June 2017 (link) recommended:

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	xxx-xxx-xx-x	Pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate	404-290-3	7216-95-7	Repr. 2 Acute Tox. 4 STOT RE 2 Eye Irrit. 2	H361d H332 H373 (Inhalation) H319	GHS08 GHS07 Wng	H361d H332 H373 H319			
RAC opinion	xxx-xxx-xx-x	Pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate	404-290-3	7216-95-7	Repr. 1B Acute Tox. 4 STOT RE 2 Eye Irrit. 2	H360D H332 H373 (Inhalation) H319	GHS08 GHS07 Dgr	H360D H332 H373 H319			
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	Pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate	404-290-3	7216-95-7	Repr. 1B Acute Tox. 4 STOT RE 2 Eye Irrit. 2	H360D H332 H373 (Inhalation) H319	GHS08 GHS07 Dgr	H360D H332 H373 H319			

Index No	Chemical Name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
603-236-00-8	ethanol, 2,2'-iminobis-, *N*-(C13-15-branched and linear alkyl) derivs.	308-208-6	97925-95-6	Repr. 1B	H360D	GHS08 Dgr	H360D			
607-733-00-0	cyflumetofen (ISO); 2-methoxyethyl (*RS*)-2-(4-*tert*-butylphenyl)-2-cyano-3-oxo-3-(α,α,α-trifluoro-*o*-tolyl)propionate	-	400882-07-7	Carc. 2 Skin Sens. 1A	H351 H317	GHS08 GHS07 Wng	H351 H317			
607-734-00-6	pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate	404-290-3	7216-95-7	Acute Tox. 4 STOT RE 2 Eye Irrit. 2	H332 H373 (inhalation) H319	GHS08 GHS07 Dgr	H332 H373 (inhalation) H319		inhalation: ATE = 1,5 mg/l (dusts or mists)	

In the case of DTPA, an early draft of the 14th ATP agreed with the RAC.

14th Adaptation to Technical Progress (ATP), the new classification of DTPA-Na5 would be:

(1) Reproductive toxicity 1B; H360D;

(2) Acute toxicity 4; H332;

(3) STOT. RE 2; H373 (inhalation).

Later on it was amended. The 14th ATP (link) (as adopted by the Commission) removed the 1B listing and instead provided only for:

The recital explains the reason(s) for this change (link):

(6) With regard to the substances pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate, carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) and pentasodium

(carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA), the classification as acute toxicant category 4 and specific target organ toxicant - repeated exposure (category 2) recommended in the RAC opinions of 9 June 2017 should be included in Annex VI to Regulation (EC) No 1272/2008, since sufficient scientific evidence is available justifying those new classifications. With regard to the substances pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate and N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid), the classification as eye irritant category 2, recommended in the RAC opinions of 9 June 2017, should be included in Annex VI to Regulation (EC) No 1272/2008, since sufficient scientific evidence is available justifying those new classifications. However, the classification of the substances pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate, N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)and pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA), a**s toxic for reproduction category 1B should not be included, since it requires further assessment by RAC in view of new scientific data on toxicity for reproduction presented by the industry after the RAC opinions were forwarded to the Commission."**(emphasis added).

Updated – Why do the new CLP rules get applied on 3 different dates?

19th February 2020
Comitology

Happy to report that it is 1 October 2021. The Commission will publish an update on 25 February 2020.

Good lawmaking is meant to be clear. I hope it is not controversial to suggest you can read the law and know when to apply it.

And, if like in the EU, where the legal texts are in different languages, you'd hope they had the same date.

Not so for the latest update to the CLP (the 14th) That's the one with TiO2 listed.

In my anglo focused head, I only read the English version (link). I looked at 9 September 2021 and thought nothing more of it.

Article 3

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 9 September 2021.

However, Article 2 shall apply from 1 December 2019.

Substances and mixtures may, before 9 September 2021, be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by this Regulation.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 October 2019.

For the Commission
The President
Jean-Claude JUNCKER

A very diligent colleague pointed out some strange anomalies. The date when the rules can be applied is on 3 different dates!

The French text, the legally binding text, forgot to add the date!

My German is appalling, but even I can work out that they sided with the English text (link).

Entrée en vigueur et application

Le présent règlement entre en vigueur le vingtième jour suivant celui de sa publication au *Journal officiel de l'Union européenne*.

Il s'applique à compter du [*OP: veuillez insérer la date, à déterminer comme suit: date d'entrée en vigueur plus 18 mois - la date devrait être le 1er jour du mois suivant.*]

Toutefois, l'article 2 est applicable à partir du 1er décembre 2019.

Les substances et les mélanges peuvent, avant le [*OP:* prière d'insérer la date spécifique d'applicabilité déterminée au deuxième paragraphe], être classés, étiquetés et emballés conformément au règlement (CE) n° 1272/2008 tel que modifié par le présent règlement.

Le présent règlement est obligatoire dans tous ses éléments et directement applicable dans tout État membre.

Fait à Bruxelles, le 4 octobre 2019.

Par la Commission
Le president
Jean-Claude JUNCKER

Artikel 3

Inkrafttreten und Anwendung

Diese Verordnung tritt am zwanzigsten Tag nach ihrer Veröffentlichung im *Amtsblatt der Europäischen Union* in Kraft.

Sie gilt ab dem 9. September 2021.

Artikel 2 gilt jedoch ab 1. Dezember 2019.

Stoffe und Gemische können vor dem 9. September 2021 in Einklang mit der Verordnung (EG) Nr. 1272/2008 in der durch die vorliegende Verordnung geänderten Fassung eingestuft, gekennzeichnet und verpackt werden.

Diese Verordnung ist in allen ihren Teilen verbindlich und gilt unmittelbar in jedem Mitgliedstaat.

Brüssel, den 4. Oktober 2019

Für die Kommission
Der Präsident
Jean-Claude JUNCKER

Most other language texts, like the Swedish version, and opt for 1 October 2021.

A few versions are based on the French text and are just not clear.

The Dutch version, which I understand okay, avoids letting us know the date of application.

I am told the Croatian and Hungarian versions follow the 'hedge your bets' line on when the law is applied.

Ikraftträdande och tillämpning

Denna förordning träder i kraft den tjugonde dagen efter det att den har offentliggjorts i *Europeiska unionens officiella tidning*.

Den ska tillämpas från och med den 1 oktober 2021.

Artikel 2 ska dock tillämpas från och med den 1 december 2019.

Ämnen och blandningar får, före den 1 oktober 2021, klassificeras, märkas och förpackas i enlighet med förordning (EG) nr 1272/2008 i dess ändrade lydelse enligt den här förordningen.

Denna förordning är till alla delar bindande och direkt tillämplig i alla medlemsstater.

Utfärdad i Bryssel den 4 oktober 2019.

På kommissionens vägnar
Jean-Claude JUNCKER
Ordförande

Artikel 3

Inwerkingtreding en toepassing

Deze verordening treedt in werking op de twintigste dag na die van de bekendmaking ervan in het *Publicatieblad van de Europese Unie*.

Zij is van toepassing vanaf [*PB: gelieve de datum in te voegen die als volgt wordt bepaald: datum van inwerkingtreding plus 18 maanden — de datum moet de 1e dag van de daaropvolgende maand zijn.*]

Artikel 2 is evenwel van toepassing met ingang van 1 december 2019.

Stoffen en mengsels mogen reeds vóór [*OP:* gelieve de in lid 2 vastgestelde specifieke datum van toepassing in te voegen] worden ingedeeld, geëtiketteerd en verpakt overeenkomstig Verordening (EG) nr. 1272/2008 zoals gewijzigd bij deze verordening.

Deze verordening is verbindend in al haar onderdelen en is rechtstreeks toepasselijk in elke lidstaat.

Gedaan te Brussel, 4 oktober 2019.

Voor de Commissie
De voorzitter
Jean-Claude JUNCKER

Hatálybalépés és alkalmazás

Ez a rendelet az *Európai Unió Hivatalos Lapjában* való kihirdetését követő huszadik napon lép hatályba.

Ez a rendelet [*Kiadóhivatal: illesszék be a következőképpen meghatározandó dátumot: a hatálybalépés dátuma plusz 18 hónap – a dátumnak a következő hónap 1. napjának kell lennie.*] napjától alkalmazandó.

A 2. cikket azonban 2019. december 1. napjától kell alkalmazni.

Az anyagok és keverékek [*Kiadóhivatal:* illesszék be az alkalmazás második bekezdésben meghatározott kezdőnapjának dátumát]. napja előtt is osztályozhatók, címkézhetők és csomagolhatók az e rendelettel módosított 1272/2008/EK rendeletnek megfelelően.

Ez a rendelet teljes egészében kötelező és közvetlenül alkalmazandó valamennyi tagállamban.

Kelt Brüsszelben, 2019. október 4-én.

a Bizottság részéről
az elnök
Jean-Claude JUNCKER

Članak 3.

Stupanje na snagu i primjena

Ova Uredba stupa na snagu dvadesetog dana od dana objave u *Službenom listu Europske unije.*

Primjenjuje se od [*Ured za publikacije: unesite datum koji se utvrđuje kako slijedi: datum stupanja na snagu plus 18 mjeseci – datum treba biti 1. dan sljedećeg mjeseca*].

Međutim, članak 2. primjenjuje se od 1. prosinca 2019.

Tvari i smjese mogu se do [*Ured za publikacije:* unesite konkretan datum primjene utvrđen u drugom stavku] razvrstavati, označivati i pakirati u skladu s Uredbom (EZ) br. 1272/2008 kako je izmijenjena ovom Uredbom.

Ova je Uredba u cijelosti obvezujuća i izravno se primjenjuje u svim državama članicama.

Sastavljeno u Bruxellesu 4. listopada 2019.

Za Komisiju
Predsjednik
Jean-Claude JUNCKER

Let's hope the Commission get publish a correction soon.

ST DOCUMENT — TEST DOCUMENT — TEST DOCUMENT — Document doesn't look right? We'll help you out! — TEST DOCUMENT — TEST DOCUMENT — TEST DOC

Some further reflections on dealing with substance classifications

1st December 2019
Comitology

I wanted to provide an update to the post of 20 November.

It's important to understand and then mirror the thinking of the decision-makers. Ignoring their world view may be purifying, but it is going to make winning your case harder.

Points 32-44 are new, as are personal observations 6 and 7. The personal observations are mine,. The rest is mainstream thinking of the vast majority of the Commission and Government officials.

Having done a few substance classifications (CLP), I get a few questions about the Commission and the Member States view the process. I have pulled together my notes and put down how the Commission and most Member States see the process.

I think it is key to understand how the people informing and making decisions see things. After all, if people saw things from your perspective, it is unlikely your substance would be looked at.

I have tidied up my scribbles below as a checklist.

1. You need to provide your science when the RAC is considering the file.
2. If you provide science after the RAC has given an opinion, the best way to re-open the file is to get a Member State to submit a new classification. There are a limited number of cases where the ECHA Executive Director re-open the file (see link).
3. Officials (Commission and Member State) are reluctant to second guess the RAC.
4. Officials don't like engaging on chemical substance; they are considered too sensitive.
5. The final outcome of the RAC will most of the most be co-opted in the ATP update.
6. Harmonised classification under CLP is about hazard classification. Risk management is not an issue.
7. The RAC's view is seen as more thorough than industry's self-classification.
8. The main first-order consequence of classification is common labelling and packaging.
9. This help provide information to the users when using the substance
10. There may be second-order impacts when classification triggers risk management in other legislation
11. You can see the list of substances classified in Annex VI (link).
12. The Commission considers they have a legal requirement to automatically transcribe the new opinions into the Annex; they contend they have no discretion. They follow this in most cases.
13. The Commission and the Member States will consider constructive suggestions to effectively translate the RAC opinion to Annex VI
14. The RAC does not rubber-stamp Member State classification dossiers.
15. ECHA transmits a consolidated list of RAC opinions at the start of the year. It's in the same format as the ATP.
16. The Commission discusses the draft adaptation to technical and scientific progress (ATP) with the expert group – CARACAL.
17. The Commission then develop the draft legal text.
18. The Commission consults with the WTO.
19. After the feedback, the Commission adopts the delegated act.
20. If you review the notes, you will see some moves to make the classification more operational.
21. Member States sometimes use the classification process as a means to get more information about a substance.
22. Even if other legislation may address any identified risks, the Commission and most Member States believe that the CLP is the appropriate regulatory instrument.
23. Socio-economic factors are seen as non-issues.
24. The Commission does not consider there is the need for an automatic impact assessment for a classification.

25. Some in the Commission question the need for a Better Regulation public consultation for a CLP update (rerun of ECHA consultation) (link)

26. Second-order impacts can only be considered under other pieces of legislation.
27. The Commission may, from time to time, undertake an assessment of the impacts of a classification.
28. A category 2 classification has limited if any direct impacts.
29. Some legislation permits the use of category 2 granting of authorisation, exemption, demonstration of safe use.
30. Ongoing procedures like substance evaluation do not detract from going ahead with the ATP listing.
31. Some Member States use the CLP as a gateway to regulatory follow-up action.
32. Just because a substance appears in nature does not mean it is safe. Many natural substances are toxic and can cause cancer.
33. The UN's GHS system does not mention any substance. All it does is lay out the criteria that are used for classifying substances. Global classification can happen by way of the WHO's IARC.
34. The EU does not cut and paste IARC's classification. There are no automatic consequences in Europe. In to other regions, like California, there is.
35. Our understanding of the hazardous properties of a substance evolves over time. Just because a substance has been used for a long time does not mean that the classification can't change.
36. The labelling requirement helps protect the health and safety of workers throughout the supply chain.
37. Other than transposal in the ATP, there is no need to consider other options.
38. Dealing with substances by way of OELs for workers protection would not cover individual consumers or the self-employed.
39. CLP gives information on hazardous properties of substances and on basic safety measures to be taken (e.g. wear gloves), while other pieces of legislation (e.g., REACH, OSH) provide more detailed risk management measures to deal with specific hazard properties identified under CLP.
40. An impact assessment on each and every substance would be difficult to perform. The current system is not set up for it. It is unlikely if industry has the data to support this exercise
41. Reducing rates of cancer has a positive economic impact. It can't be ignored.
42. There are significant downstream impacts for classification carcinogen category 1 (known or presumed carcinogen), but for carcinogens category 2 (suspected human carcinogens), there are no such significant direct consequences.
43. For some legislation, category 2 carcinogen (suspected human carcinogens) the legislation (e.g. plant protection products, biocidal products, food additives, contaminants, water and pharmaceuticals), there are no or minor consequences.
44. For other another group of legislation (food contact materials, plastic food contact materials, toys, feed additives, cosmetics and EU Ecolabel), category 2 means you need the granting of authorisation, exemption, and the demonstration of safe use.

A few personal observations:

1. The key window of opportunity is the deliberations of the RAC and their final opinion.
2. The best way to engage is with a significant and long-established body of world-class science on all substance endpoints. As a rule of thumb, I take ten years as the minimum level.
3. Coming in late or not at all is unlikely going to work out well.
4. Saying you are right and the RAC is wrong are pleases that to fall on deaf ears.
5. The burden of bringing new science to the table to re-open a RAC opinion is very high.
6. Civil servants and politicians are reluctant to engage on chemicals.
7. They are more reluctant to engage if 'cancer' is mentioned.

Lessons in Lobbying #19: Follow a system, not your emotions, when lobbying

10th April 2022
Good Practice

The first thing I ask every new client is what type of proposal they are dealing with and where is the proposal in the adoption process.

I do so for two simple reasons.

First, as soon as you are clear about what type of initiative you are dealing with, the steps and actions you need to take are very clear. I turn to a collection of process charts, checklists and case studies, and can more or less give an accurate diagnosis on the chances of success and the next actions.

Second, the later you step in, the less chance you have to influence events. My Catholic guilt has forced me too many times to say "I can't help because it is too late in the process". Fortunately, there are more than enough lobbyists and lawyers to say I am wrong and take on the fight. To date, none have succeeded.

It means there is no one map and approach that works. But, if you have a set of well-tested maps (checklists, process charts, case studies), that have been tried and tested and work, your chance of getting to where you want to be are a lot higher than if you don't.

A Mechanical Approach

If you really understand the mechanics of how laws and policies are really adopted and passed, you don't leave things to chance. A lot of people find this mechanical approach dull and prefer a more free-flowing approach, driven by their gut and emotions. With age, I've found if you have mechanics perfected, know what to do and when you have a lot more headspace for 'exciting' things.

I mainly work on a mix of secondary legislation and ordinary legislation.

The majority of my work is secondary legislation dealing with substance issues.

So, I tend to deal with a lot of ECHA Agency work. This means the work is divided into two stages, the deliberative work in Helsinki, and the adoption work in Brussels. The opinion-making and then the adoption by secondary legislation. Each has its own process, dynamic, and requires different information to be brought to different people at different times.

The steps for a CLP Classification, REACH Restriction, REACH Authorisation, or REACH SHVC Identification, are clear.

The actions you need to take for each of the procedures are as clear. If you want to ignore these steps and right actions, you can't be surprised if things don't go your way.

When you are dealing with any CLP or REACH measure, all you are really dealing with is a piece of secondary legislation.

Summary

CLP Classification: Delegated act

REACH Restriction: RPS Measure

REACH Authorisation: Implementing act

REACH SHV Identification: Implementing act

For a list of procedures, please go here.

So, all you have to do for each is turn to a good process chart that spells out all the steps, makes clear all the actions needed, and offers you a clear process map, checklists and case studies on what success looks like.

Be Ahead of the Curve

The only difficulty is that a lot of the material you need to make your case will be needed years before any proposal is made. The timelines to prepare your case, and create the right evidence, are often too short to bring new and pertinent evidence to the table. So, this requires that you are constantly attentive to new scientific developments and political winds, and are on alert, and ready to prepare your case when the winds change. If you wait until a proposal is made public, you are likely too late.

The same goes for ordinary legislation. The steps in the ideation, adoption and legislative passage of a proposal are well laid out. The actions you need to take are well known, if not often practised.

The direction of travel is locked in early on. It is possible to insert or derail but is very difficult. If you have the resources to pull this off.

The Key Steps Are Not Public

Just as with a recipe, the adoption of legislative proposals follows a number of steps. Those steps are particular for each and every recipe, and the steps for the adoption of each type of law are more or less the same. There will be variations. The politics and the issue and of course the votes for her against the proposal well to some degree rather be different. But, what is not different, are the steps that happen. The steps for an implementing act, delegated act, RPS Measure, or ordinary legislation, are different. The actions you need to take and when are not the same.

What is clear when you look at the anatomy of a legislative proposal from ideation, adoption and political agreement, the public steps are a small part of the overall process.

It is like looking at the skeleton of a human being and proclaiming the bones as a living breathing human. But that skeleton misses the sinews, nerves, blood, muscles, and organs, let alone the soul of life itself of a fully functioning sentient human being.

Too much lobbying and campaigning proceed as if the skeleton is everything. And, as such misses out and all but the most important steps and the actions that you can take to influence the process.

The one reason to Lobby

Lest we forget, the purpose of lobbying is so that your client can influence the final outcome of the policy and law. It is not, as so many seem to think, an opportunity for bellybutton gazing, the healing and gnashing of teeth in marathon internal meetings. Your sole objective should be to ensure that the final policy or law put onto the statute books/Official Journal, is the one that you want.

Those minded for aspirations for perfection on this political Earth, should perhaps seek a more spiritual vocation of a think tank, University cloister, or a take a vow of political celibacy and become a Party activist. There the torments of this political world can be dealt with by political recitations of faith, or in the privacy of one's own room, political self-flagellation. But if you are minded to do this, you should at all costs avoid entering the world of lobbying. The disappointments will be too much for you.

One Challenge

There is only one challenge. Few of the key steps are public. And, more importantly, the small windows of opportunity that you have to influence the direction of travel are often not public. But, if you don't know the real steps in the first place, it is going to be hard to find out what actions you need to take or have any real influence.

If you do follow this approach, your chances of embracing success are high. It is an approach that time, persistence and self-realism.

Section 2

16th February 2023
Uncategorised

Lessons in Comitology – Challenges in relation to chemicals

28th June 2019
Comitology

Just before the new European Parliament starts work, it's a good time to look at the successful challenges to secondary legislation dealing with chemicals by the European Parliament.

I have looked at five successful challenges in the last Parliament: four REACH Authorisations and one RoHS exemption.

The Council did not raise any objections on secondary legislation about chemical substances.

Some General Observations

Reading the objections they focus on:

- A substantive error of law
- Procedural errors
- Ignored something obvious that should have been taken into account

Most of the successful challenges, in general, are around public health issues.

In the main, they mirror the three grounds to challenge a RPS draft: 1. excess of implementing powers, 2. Violation of the aim or content of the legislation, and 3. violation of subsidiarity or proportionality.

It is not easy to mount a successful challenge. The challenge has to be launched quickly after the Commission transfers the text to the European Parliament. It is clear that challenges are not launched on a whim. They are not vexatious.

The challenges secure cross Party support, although the challenges are launched by the Greens and S&D. The size of support in the environment committee and in the full Parliament is often considerable.

If you want to challenge a measure, you are going to have to jump over some very high procedural hurdles.

In the European Parliament, you are going to have to:

1. Find someone to support you
2. Get it past the lead Committee (environment for chemicals), and if passed
3. Get 376 votes for RPS and Delegated acts or majority for implementing acts. To see how hard this threshold see this piece on Canadian Oil Sands challenge

Specific Observations

First, the challenges are specific, well reasoned and detailed.

Second, they often highlight the availability of substitutes.

Third, they ask for a more narrow authorisation rather than a simply scrapping it. Indeed, in some, they acknowledge that need for some uses but draw a line about broad or generic derogations.

Finally, one person is behind every successful challenge.

Case Studies

1. **27 March 2019: Objection pursuant to Rule 106: Certain uses of bis(2-ethylhexyl) phthalate (DEHP) (DEZA**

Measure: Implementing act

Objection by: Poc (S&D), Konečná (GUE), Eickhout (Greens/EFA)

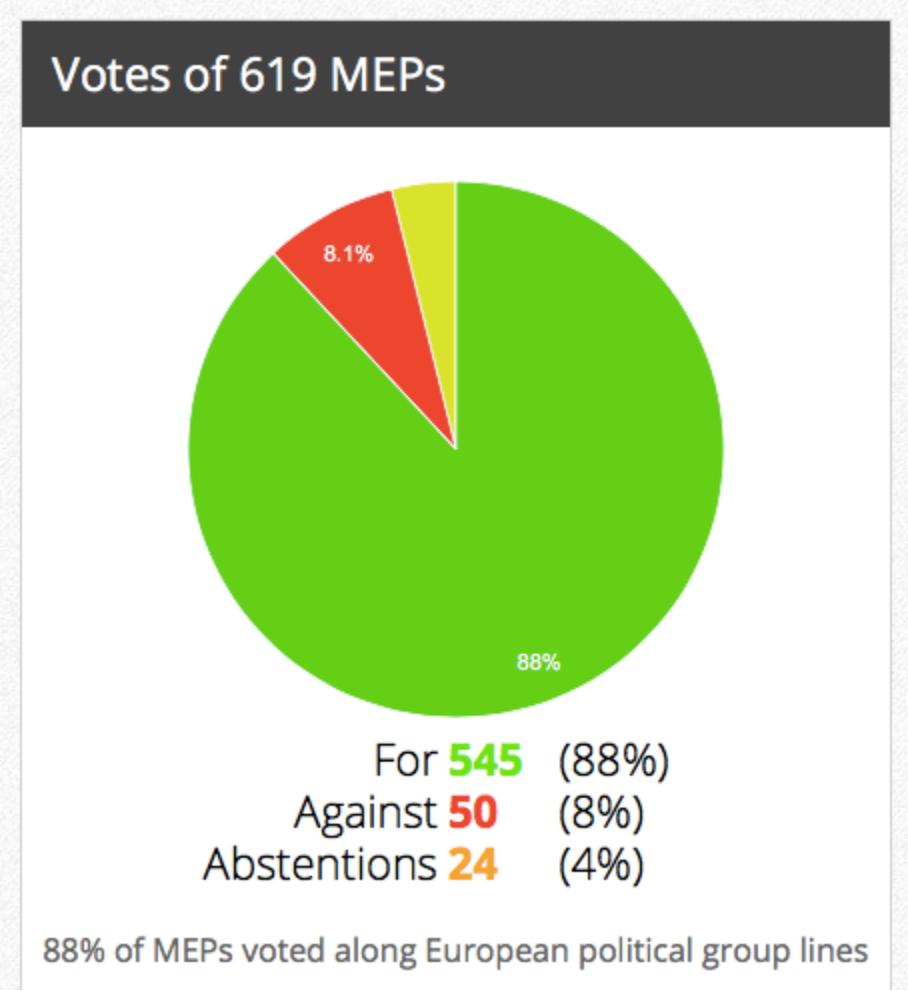
Committee vote: 14 March 2019

Adopted: 39 in favour, 2 against and 1 abstention

Plenary Vote: 27 March 2019

Adopted: For: 545, Against: 50, Abstentions: 24

Vote Watch Link



Group	For	Against	Abstentions	Total present	Total absent	Total non voters	Total members	Cohesion
ALDE/ADLE	53	3	2	58	0	10	68	87.07
ECR	39	20	3	62	0	13	75	44.35
EFDD	22	0	15	37	0	4	41	39.19
ENF	29	0	1	30	0	7	37	95
EPP	150	22	2	174	0	43	217	79.31
Greens/EFA	47	0	0	47	0	5	52	100
GUE-NGL	38	0	0	38	0	14	52	100
NI	10	3	1	14	0	8	22	57.14
S&D	157	2	0	159	0	27	186	98.11

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European Parliament

2014-2019

TEXTS ADOPTED

Provisional edition

P8_TA-PROV(2019)0315

Certain uses of bis(2-ethylhexyl) phthalate (DEHP) (DEZA a.s.)

European Parliament resolution of 27 March 2019 on the draft Commission implementing decision partially granting an authorisation for certain uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (DEZA a.s.) (D060865/01 – 2019/2605(RSP))

The European Parliament

– having regard to the draft Commission implementing decision partially granting an authorisation for certain uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (DEZA a.s.) (D060865/01),

2. 27 March 2019: Objection pursuant to Rule 106: Certain uses of bis(2-ethylhexyl) phthalate (DEHP) (Grupa Azoty)

Measure: Implementing act

Objection by: Poc (S&D), Konečná (GUE), Eickhout (Greens/EFA)

Committee vote: 14 March 2019

Adopted: 42 in favour, 0 against and 1 abstention

Plenary Vote: 27 March 2019

Adopted: Carried by a show of hands

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European Parliament

2014-2019

TEXTS ADOPTED

Provisional edition

P8_TA-PROV(2019)0316

Certain uses of bis(2-ethylhexyl) phthalate (DEHP) (Grupa Azoty Zakłady Azotowe Kędzierzyn S.A.)

European Parliament resolution of 27 March 2019 on the draft Commission implementing decision partially granting an authorisation for certain uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Grupa Azoty Zakłady Azotowe Kędzierzyn S.A.) (D060866/01 – 2019/2606(RSP))

EP objection authorisation DEHP Grupa 27 March 2019

3. 27 March 2019: Objection pursuant to Rule 106: Certain uses of chromium trioxide

Measure: Implementing act

Objection by: Eickhout (Greens/EFA)

Committee vote: 21 March 2019

The European Parliament,

– having regard to the draft Commission implementing decision partially granting an authorisation for certain uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Grupa Azoty Zakłady Azotowe Kędzierzyn S.A.) (D060866/01 – 2019/2606(RSP)),

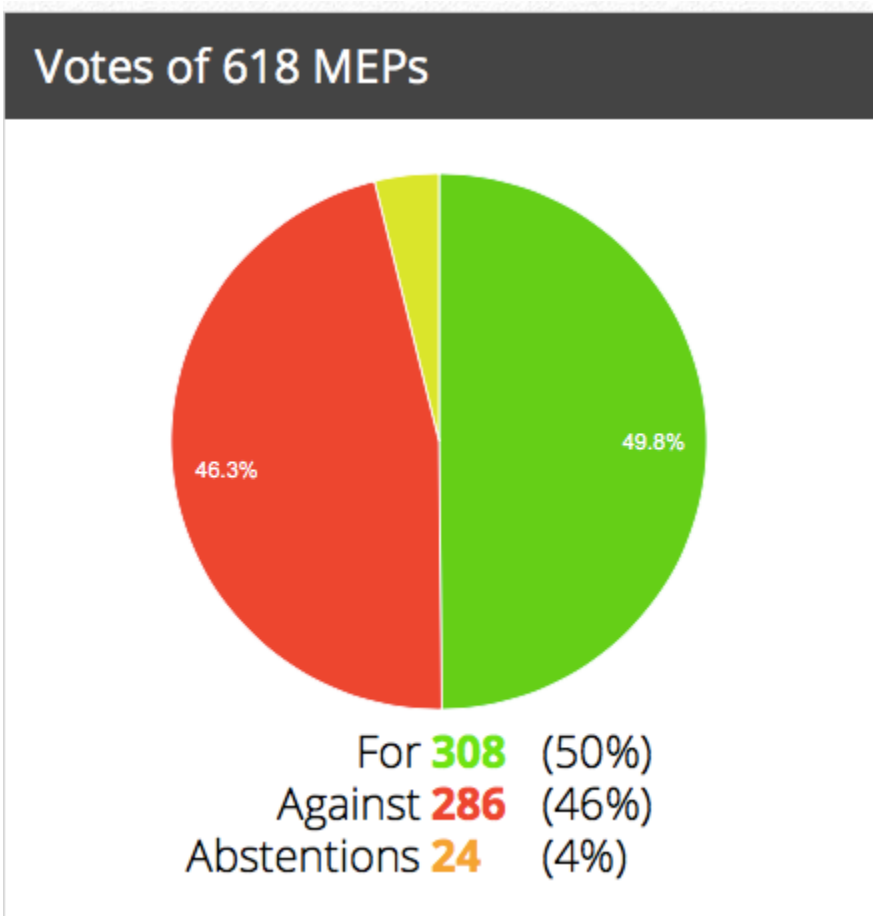
– having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93

Adopted: for: 20, against 16, abstentions 3

Plenary Vote: 27 March 2019

Adopted: For: 309, Against: 286, Abstentions: 24

Vote Watch Link



Group	For	Against	Abstentions	Total present	Total absent	Total non voters	Total members	Cohesion
ALDE/ADLE	34	21	0	55	0	13	68	42.73
ECR	5	55	2	62	0	13	75	83.06
EFDD	21	2	14	37	0	4	41	35.14
ENF	29	1	0	30	0	7	37	95
EPP	10	163	3	176	0	41	217	88.92
Greens/EFA	47	0	0	47	0	5	52	100
GUE-NGL	36	0	3	39	0	13	52	88.46
NI	8	6	0	14	0	8	22	35.71
S&D	119	38	2	159	0	27	186	62.26

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European Parliament
2014-2019

TEXTS ADOPTED
Provisional edition

P8_TA-PROV(2019)0317

Certain uses of chromium trioxide

European Parliament resolution of 27 March 2019 on the draft Commission implementing decision granting an authorisation for certain uses of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Lanxess Deutschland GmbH and others) (D060095/03 – 2019/2654(RSP))

The European Parliament

– having regard to the draft Commission implementing decision granting an authorisation for certain uses of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Lanxess Deutschland GmbH and others) (D060095/03),

4. 29 November 2018: Authorisation for certain uses of sodium dichromate (link)

Measure: Implementing act

Objection by: Eickhout (Greens), Poc (S&D), Pudney (ALDE)

Committee Vote: 20 November 2018

Adopted by: 24; against: 0; abstentions: 17.

Plenary Vote: Adopted by a show of hands

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European Parliament

2014-2019

TEXTS ADOPTED

Provisional edition

P8_TA-PROV(2018)0474

Authorisation for certain uses of sodium dichromate

European Parliament resolution of 29 November 2018 on the draft Commission implementing decision granting an authorisation for certain uses of sodium dichromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Ilario Ormezzano Sai S.R.L.) (D058762/01 – 2018/2929(RSP))

The European Parliament,

EP resolution objection Ormezzano 29 Nov 2018

5. 25 November 2015: **Authorisation for uses of bis(2-ethylhexyl) phthalate (DEHP)**

Measure: Implementing act

Objection by: Poc (S&D)

Committee vote: 10 November 2015

Adopted by: 58 for, 5 against, 0 abstention

Plenary Vote: 25 November 2015

Adopted: For 603 for, against 86, abstentions 5

Majority needed: simple majority 345

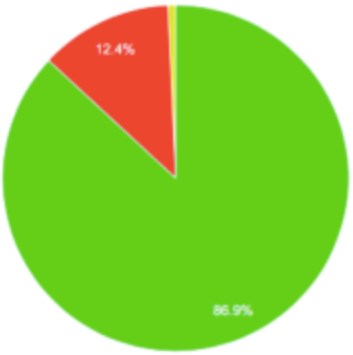
EU Vote Watch link

having regard to the draft Commission implementing decision granting an authorisation for certain uses of sodium dichromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Ilario Ormezzano Sai S.R.L.) (D058762/01),

– having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1] ('the REACH Regulation'), in particular Article 64(8) thereof,

having regard to the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC)[2], pursuant to the third subparagraph of Article 64(5) of the REACH Regulation,

– having regard to Articles 11 and 13 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[3],



For 603 (87%)
Against 86 (12%)
Abstentions 5 (1%)

EP objection authorisation DEHP 25 Nov 2015

20 May 2015: Exemption for cadmium in illumination and display lighting applications

Measure: Delegated act

Objectors: Eickhout, Taylor (Greens/ALE), Groote, Sârbu, Poc, Dance, Melior, Guteland (S&D Group), Konečná (GUE)

Committee Vote: 13 May 2015

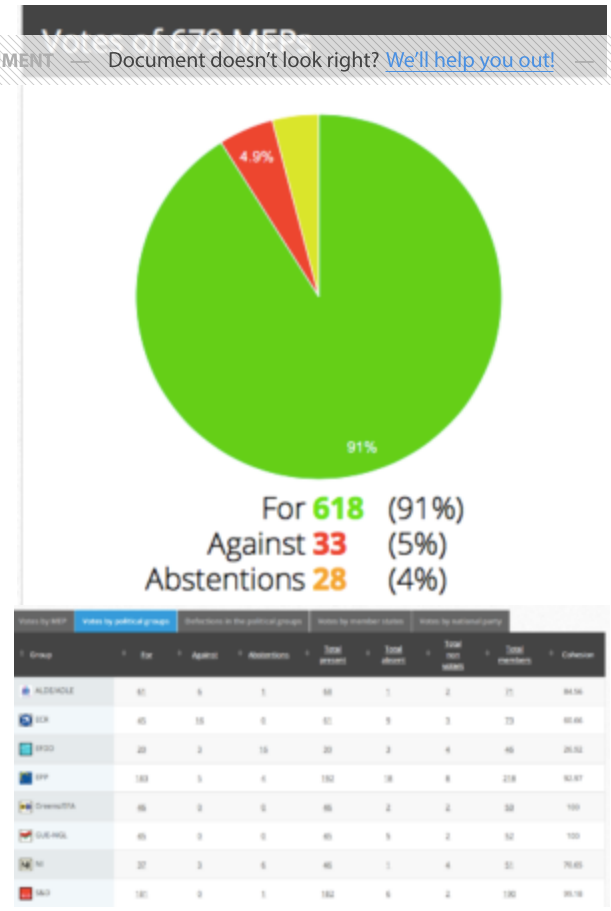
Adopted: unclear

Plenary Committee Vote: 20 May 2015

Adopted by 618 for, 33 against, 28 abstentions

Majority needed: 376

EU Vote Watch link



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European Parliament
2014 - 2019

TEXTS ADOPTED

P8_TA(2015)0205

Objection to a delegated act: exemption for cadmium in illumination and display lighting applications

European Parliament resolution of 20 May 2015 on the Commission delegated directive of 30 January 2015 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium in illumination and display lighting applications (C(2015)00383 – 2015/2542(DEA))

exemption for cadmium in illumination and display lighting applications 20 May 2015

The European Parliament,

– having regard to the Commission delegated directive (C(2015)00383),

– having regard to Article 290 of the Treaty on the Functioning of the European Union,

– having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and in particular Articles 4, 5(1)(a) and 22 thereof[1],

– having regard to Rule 105(4) of its Rules of Procedure,

A. whereas Article 4(1) of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment ('RoHS') restricts inter alia the use of cadmium in electrical and electronic equipment (see the listing in Annex II to the RoHS Directive);

B. whereas Annex III to the RoHS Directive provides for exemptions from the restrictions laid down in Article 4(1);

VI LEDs (< 10 µg Cd per mm2 of light-emitting area) for use in solid state illumination or display systems' with an expiry date of 1 July 2014;

D. whereas Article 5 provides for the adaptation to scientific and technical progress of Annex III for the inclusion and deletion of exemptions;

Delegated Acts – Grounds for Successful Challenges

22nd July 2019
Comitology

In this piece, I look at the grounds for the successful challenge and look to provide more background.

Grounds: legal and Commission stepping into Member States' competence.

Everything below is based on publically available sources. It's just a time-consuming process.

The development of the files shows a lack of political deft touch by the Commission Services. To see so much work thrown away shows that the Commission's internal scrutiny system is wanting.

An indication that pushing delegated acts adoption through quickly and without taking on board concerns is dangerous.

Whilst most objections are grounded in solid legal or procedural concerns, the lack of grounds to challenge a delegated acts has been used on some occasions.

Any Council format can formalise the objection with a decision.

There is a short window of opportunity to bring about the challenge.

The EP is likened to ask for a partial re-assessment and not a total veto

Council – Successful Challenges

Case 1: supplementing Directive 2010/40/EU of the European Parliament and of the Council with regard to the deployment and operational use of cooperative intelligent transport systems (link)

Grounds: Legal (see link)and technological

- 8 July 2019: Council – Employment and Social Policy – back objection (link)
- 13 July 2019: Deadline to object (2+2)
- 4 July 2019: CORPRER discuss. Chair identifies a QMV in support of the objection
- 26 June 2019: Intermodal Transport Working Party discuss DA in the light of the opinion4 prepared by the Council Legal Service. Seven delegations express intention to object. Four delegations express support.
- 13 May 2019: Scrutiny period extended by two months by Council of the EU
- 8 May 2019: Presidency asks for two months extension
- 3 May 2019: Intermodal Transport Working Party discuss
- 17 April 2019: Motion for a resolution tabled by the TRAN Committee rejected by Plenary (link)Votes: 270 for, 304 against, 30 abstentions (link)
- 8 April 2019: TRAN Committee Resolution adopted by Committee (link)grounds: procedural (transmitted just before the recess (f)) and technological (d) (link), Roll Call Vote: 16 for, 11 against, and 4 abstentions (link)
- 5 April 2019: Intermodal Transport Working Party discuss – 4 countries plus others ask for Council Legal Service Opinion
- 3 April 2019: Deadline for delegations to raise objections – 4 comments received
- 3 March 2019: Commission submit delegated act to Council and European Parliament
- 13 March 2019: Impact Assessment published and Executive Summary
- 13 March 2019: Delegated act adopted
- 8 February 2019: public consultation ends – 100 submissions
- 11 January 2019: 4-week draft delegated act public consultation starts
- 9 February 2018: Stakeholder Consultation
- 12 January 2018: Public Consultation ends
- December 2018: RICARDO Study ends10 October 2018: RSB issue opinion on Impact Assessment (Positive with Reservations)
- 12 October 2017: 2nd meeting of the Expert Group for Preparation of the delegated act

- 10 October 2017: Public Consultation starts (13 weeks)
- September 2017: Contract to RICARDO issued to provide a support study for IA
- 25 May 2017: First meeting of the Expert Group for Preparation of delegated act
- 20 March 2017: New delegated act planned
- 30 November 2016: Commission Communication announce delegated act by 2018 (link)
- 7 July 2010: Directive 2010/40/EU published in OJ (link)

Case 2: 6 June 2019: measures adopted by the International Civil Aviation Organisation for the monitoring, reporting and verification of aviation emissions for the purpose of implementing a global market-based measure – Council (link)

Grounds: Legal concerns, (no conflict with Chicago Convention) substantive: Commission stepping into Member States' competence and sets a precedent for other international fora.

18 July 2019: Commission adopt a new delegated act taking into account reservations rasied by Member States

6 June 2019: Justice and Home Affairs Council agree to objection without debate, adopted as an A Point. 24 Member States sign the statement.

29 May 2019: COREPER confirm t decision to object to the measure

23 May 2019: Scrutiny phase extended 1 month

15 May: COREPER discuss file – 18 Member States (QMV) sign statement expressing

8 May 2019: Working Party on the Environment discuss file

15 April 2019: Agriculture and Fisheries Council adopt a decision to extend scrutiny by an extra month

11 April 2019: COREPER supports the call for 1 more month

4 April 2019: Working Party on the Environment discuss the measure and ask for 1 more month

6 March 2019: Delegated act adopted

26 December 2018: Public Consultation ends

27 November 2018: 4 weeks Public Consultation starts (link)

27 November 2018: Draft Delegated act

13 July 2018: Meeting of the Climate Change Expert Group

13 November 2017: New delegated act planned

Case 3: 7 March 2019: supplementing Directive (EU) 2015/849 of the European Parliament and of the Council by identifying high-risk third countries with strategic deficiencies (link)

Grounds: Political sensitivity, lack of consultation with the Member States, lack of consultation with third countries

7 March 2019: Justice and Home Affairs (JHA) Council object (28 Member States)

6 March 2019: COREPER back position to object

13 March 2019: Deadline for EP and Council to object (extension by 1 month)

28 February 2019: 27 Member States announce that they will object to the proposal

13 February 2019: Delegated act adopted

7 February 2019: Expert Group provide further feedback

5 February 2019: Expert Group discuss the draft delegated act

28 January 2019: Commission consults Expert Group by written procedure (until 1 February 2019)

23 January 2019: Commission inform third countries of inclusion

15 November 2018: Commission publishes results (link)

29 October 2018: Written Procedure for Expert Group of the first group of countries

15 September 2018: Expert Group endorse Commission approach

June 2018: Last meeting of Expert Group

30 May 2018: European Parliament and Council adopt Directive (EU) 2018/843,

30 June 2017: Road Map

December 2017: Start of Expert Group consulted on approach, methodology and assessment criteria

Case 4: 7 November 2014: on the transmission format for research and development expenditure data, as referred to in Regulation (EU) No 549/2013 of the European Parliament and of the Council on the European System of national and regional accounts in the European Union (link)

07 November 2014: Council adopt objection

12 August 2014: Delegated act adopted

Case 5: 9 December 2013: GalileoÂ (link)

Grounds: Legal, sovereigntyu

5 January 2014: Deadline for objection (as extended)

9 December 2013: Council adopt objection (link)

29 November 2013: 25 Member States support objection

27 November 2013: Information Written Procedure launched for the Member States

27 November 2013: Working Party on Intermodal Questions and Network meet. 14 Member States indicate opposition to the delegated act

5 November 2013: Deadline for objection (initial) objection

19 September: EP extends the deadline by two months for objection to 5 January

06 September 2013: Delegated act adopted

European Parliament Successful Challenges

Case 6: 27 March 2019: amending Annex II to Regulation (EU) No 516/2014 of the European Parliament and of the Council establishing the Asylum, Migration and Integration Fund (link)

Case 7: 27 March 2019: amending Annex II to Regulation (EU) No 515/2014 of the European Parliament and of the Council establishing as part of the Internal Security Fund, the instrument for financial support for external borders and visa (link)

Grounds: Legal and political

28 March 2019: Resolution adopted (link)

20 March 2019: Civil Liberties Committee Motion for Resolution adopted

14 December 2018: Delegated act adopted

24 September 2018: Draft delegated act

Case 8: 14 June 2018: amending Delegated Regulation (EU) 2017/118 establishing fisheries conservation measures for the protection of the marine environment in the North Sea (link)

Case 9: 17 May 2017: amending Delegated Regulation (EU) 2016/1675 supplementing Directive (EU) 2015/849 of the European Parliament and of the Council, as regards deleting Guyana from the table in point I of the Annex and adding Ethiopia to that table (link)

Case 10: 19 January 2017: amending Commission Delegated Regulation (EU) 2016/1675 supplementing Directive (EU) 2015/849 by identifying high-risk third countries with strategic deficiencies (link)

19 January 2017: Resolution adoption. 393 for, 67 against, 210 abstenstions.

Case 11: 14 September 2016: on key information documents for packaged retail and insurance-based investment products (PRIIPs) by laying down regulatory technical standards with regard to the presentation, content, review and revision of key information documents and the conditions for fulfilling the requirement to provide such documents (link)

Case 12: 20 January 2016: supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for processed cereal-based food and baby food (link)

Case 13: 20 May 2015: amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium in illumination and display lighting applicationsÂ (link)

Grounds: Manifest error of fact, requestassessment

20 May 2015: Objection adopted, 618 for, 33 against, 28 abstentions

13 May 2015: Objectors: Eickhout, Taylor (Greens/ALE), Groote, Sârbu, Poc, Dance, Melior, Guteland (S&D Group), Konečná (GUE)

30 January 2015: Delegated act adopted

Case 14: 20 May 2015: regards the obligation to present a licence for imports of ethyl alcohol of agricultural origin and repealing Regulation (EC) No 2336/2003 introducing certain detailed rules for applying Council Regulation (EC) No 670/2003 laying down specific measures concerning the market in ethyl alcohol of agricultural origin (link)

Grounds: Political

20 May 2015: European Parliament objection adopted (link) 486 for, 164 against, and 26 abstenstions

7 May 2015: Michel Dantin, Eric Andrieu, José Bové, Martin Häusling on behalf of the Committee on Agriculture and Rural Development table objection

20 February 2015: Delegated act adopted

Case 15: 15 January 2014: on the provision of food information to consumers as regards the definition of 'engineered nanomaterials (link)

Grounds: Legal – exceeds delegated powers and not compatiable with the aim and content of the enabling legislation

12 April 2014: Deadline for objections

19 March 2014: COREPER decided not to object. No QMV to object.

12 March 2014: Objection adopted (link) 402 for, 258 against, and 14 abstentions.

28 February 2014: Council Working Party discuss the objection

19 February 2014: Council Working Party discuss the objection

12 February 2014: Environment Committee adopts resolution: 31 for, 26 against and 2 abstentions

5 February: Motion for a Resolution tabled by Carl Schlyter, Åsa Westlund, Kartika Tamara Liotard, Christa Klaß, Sirpa Pietikäinen, Frédérique Ries

3 February: Environment Committee indicate intention to raise objection

22 January 2014: COREPER support extension

17 January 2014: Council Working Party on Foodstuffs discuss and ask for a 2-month extension

20 December 2013: Corrigendum published correcting the error

19 December 2013: Delegated act published in OJ (by accident)

12 December 2013: EP and Council receive delegated act – 2 months (extendable by 2 months)

12 December 2013: Delegated act adopted

10 November 2013: Deadline for feedback from WTO

11 September 2013: Commission notifies WTO of draft delegated Regulation

6 September 2013: Inter-Service Consultation ends

26 July 2013: Draft delegated act in inter-service consultation

24 May 2013: Commission Expert Group discuss the draft definition

22 May 2013: Working Group within the Advisory Group on the Food Chain and Animal and Plant Health discuss the definition

What to do if the Commission's delegated legislation proposal is against you?

16th May 2016
EU

Provisional Draft

I have had the good fortune to advise NGOs and industry as a lobbyist. I have often been asked what can be done when the Commission is about to make a proposal that is against their interests.

2 Minutes to Midnight

I am often asked this question just before, and usually just after, the Commission has made the proposal.

If you really want to change the Commission's long term thinking you need to change their thinking. That takes a long term perspective and feeding in fresh thinking and solutions at the Brussels and Member State level. I have found it the surest way of brining about positive proposals from the Commission. But, perhaps because it takes a few years before you can measure your success, most organisations, NGOs and companies do not go down this path.

Delegated legislation

I am most interested in what happens if the Commission is going to table a piece of delegated legislation that is against your interests.

The truth is that if the Commission are about to, or have just tabled tabled, a proposal for delegated legislation that is against your interests, you are in a bad place. The Commission usually get what they want, and the chances of changing their mind or having their proposal blocked are slim.

Whilst the chances to block the Commission are slim, they are not impossible, and I'll share some thoughts on securing what you may want.

The odds that the European Parliament or Member States will step in and block the Commission's delegated legislation proposal are less than 1%. For ordinary legislation, the Commission have a tougher ride, and whilst only a few ordinary legislative proposals fall, important elements of their original legislative package can be altered.

First, read this

Usually, I'd advise two immediate steps:

First, you should read Daniel Guegen & Vicky Marissen's Handbook on EU secondary legislation. You should aslso read Guegen's excellent book "The Orphacol Saga" (available here).

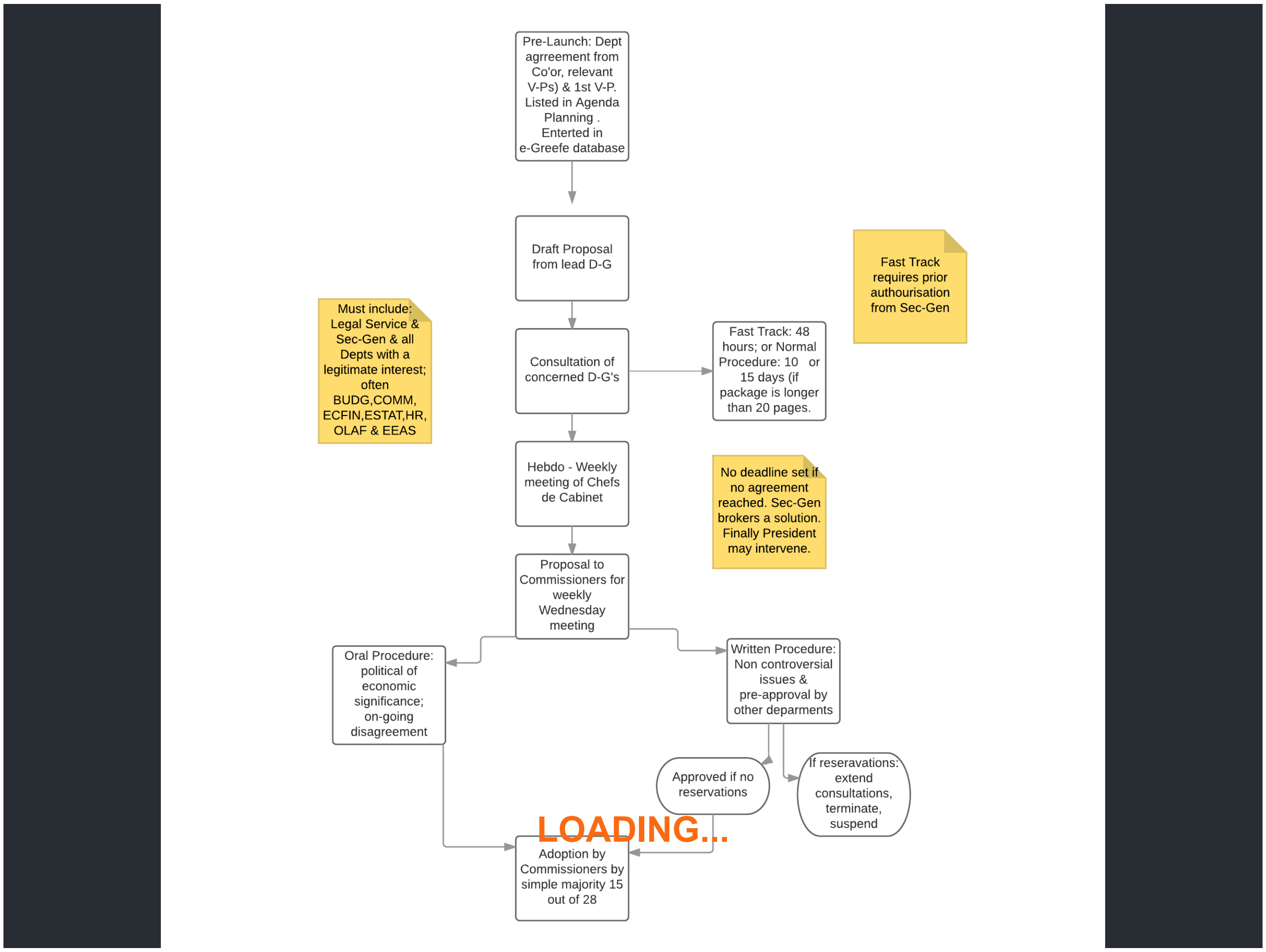
If after reading that, you are not in despair about what you need to reverse things, and you are serious enough to realise that just praying that things will change (they may, but don't usually don't) you may find some helpful suggestions below.

A Warning

What I recommend is not for the feint hearted. It requires speaking to a lot of people, usually early on the the process, to secure the changes you want. The toughest part is that what is important for you is usually not that important important to the European officials, national civil servants and politicians you will need to support you. What drives them to act will usually be factors separate than your own. You will need to change your story and case to most resonate with the people you are speaking with.

Step 1 Inter- Service Consultation

Please see my earlier blog on influencing Inter-Service Consultation here.



The greatest challenge for most organisations, NGOs and trade associations is twofold.
First, having an agreed position which they can speedily deploy. Inter-Service Consultation will last 2 /3 weeks, 3 or 48 hours. Many organisations have a hard time getting internal sign off that quickly.

Second, the people dealing with the adoption of the proposal are 4 groups of people: 1. Commission officials, 2. Cabinet leads on the file, 3. Heads of Cabinet, and 4. Commissioners. Given this audience it is remarkable how often organisations deploy long (more than 2 pages) technical briefings. I have found it helpful to appeal to their professional background, which is usually generalists, lawyers, or political players, and speak to those points. On the occasions the issue is scientific or technical making the issue make sense to a normal person rather than an scientific/technical expert is key. It is remarkable how often people want to display their intricate knowledge of their doctoral thesis, usually in a field which makes quantum physics seem simple, and loose the Cabinet lead. It is always useful to remember that this is all about persuading people to take up your position /agenda and not to loose them.

Third, sometimes proposals may have advanced to the final adoption phase without going through the internal procedures. I have seen proposals that were about to be adopted that had not gone through inter-service consultation or been validated by the 1st Vice President. If you find a procedural anomaly, it is worth highlighting that at the very start. Good civil servants never like procedures being ignored or broken.

Step 2 – After the proposal is put forward

If the Commission table a piece of delegated legislation you do not support you are now climbing up a very steep hill.

You will need to work with the European Parliament, or the Member States, or both, to block the Commission's proposal.

The European Parliament are more active at blocking Commission proposals compared to the Member States.

In the last European Parliament EP), the EP blocked 4 Regulatory Procedure with Scrutiny proposals, and 1 Delegated Act. The EP have not been able to force the Commission to withdraw an Implementing Act proposal.

The Council have more reticence in challenging the Commission's proposal.

I will later edit this blog and add examples where the Council have intervened to block a Commission's delegated measure.

The first question you need to ask is: What process is the delegated legislative proposal being adopted under. Is it:

1. A Delegated Act
2. An Implementing Act
3. Regulatory Procedure with Scrutiny

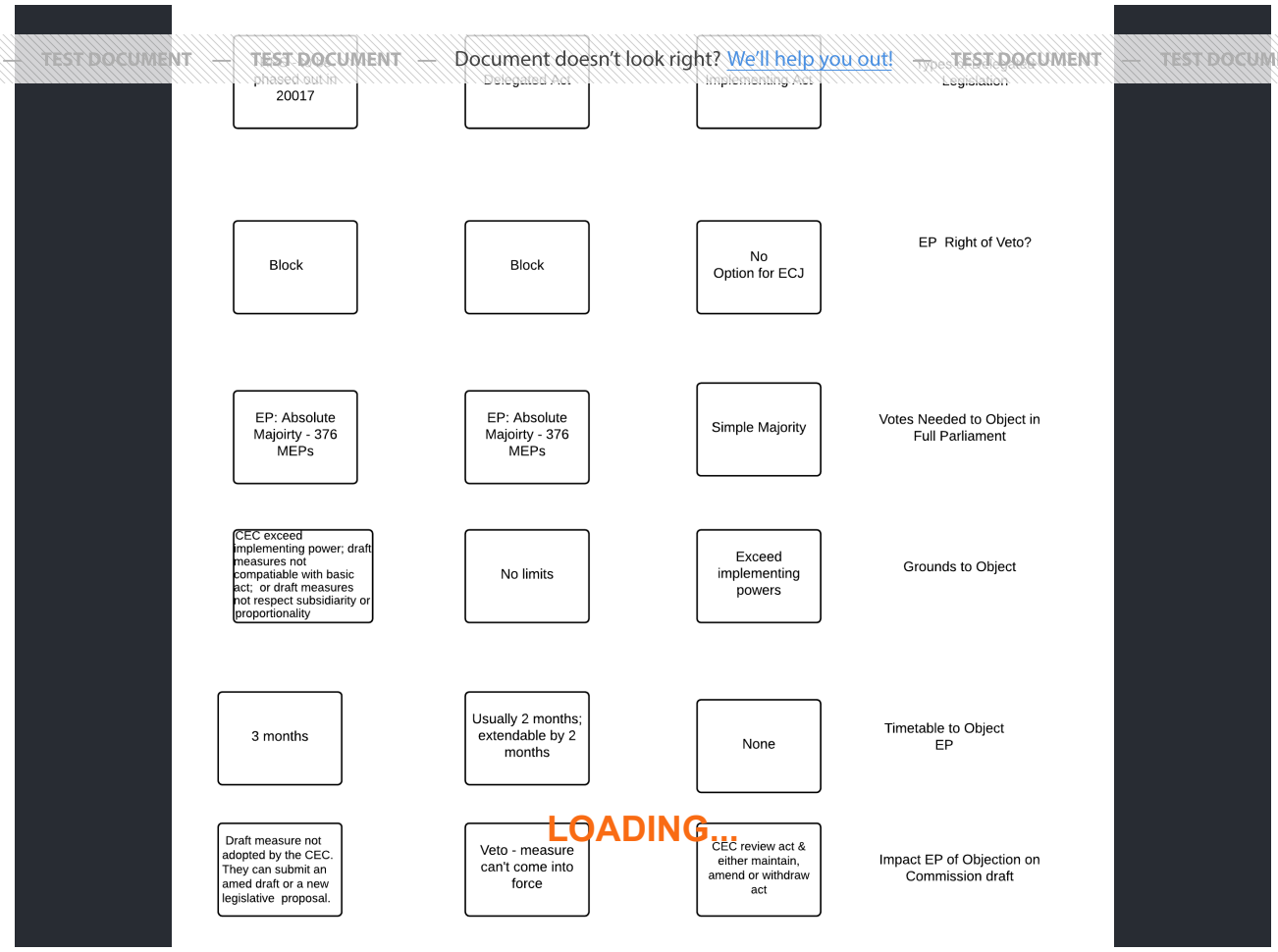
I'll explore each option below.

These charts are broad brush maps. They provide you with an idea of the journey, but the actual maps will be specific for each case, and far more granular. These maps for example do not detail the mechanics of how a European Parliament Committees or Council Working Working challenge a delegated measure.

Overview

Below is a summary for how the EP and the Member States can intervene and the impact of their intervention.

Overview of the EP



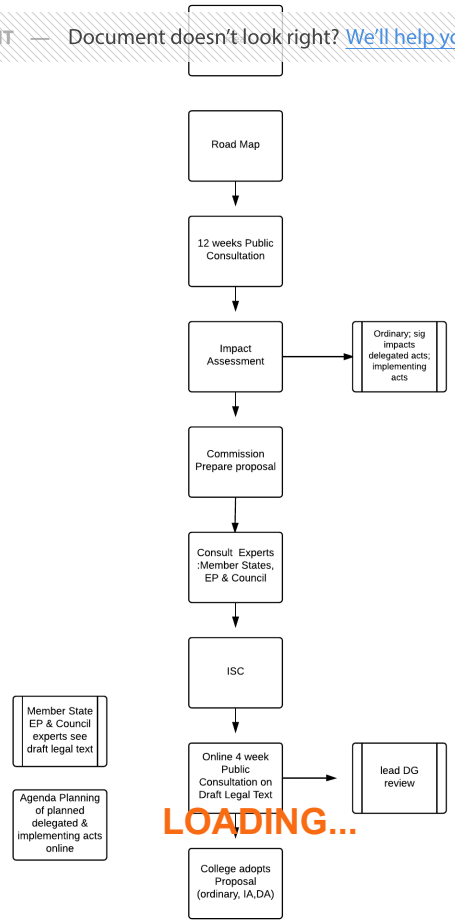
Overview of the Member States

To be added

Better Law Making Agreement

As I have written before (see here), the Better Making Agreement has established important changes to how the Commission adopt delegated legislation. This secretive law making process will be opened up from 1st July 2016.

Please see a process chart below indicating some of those changes.



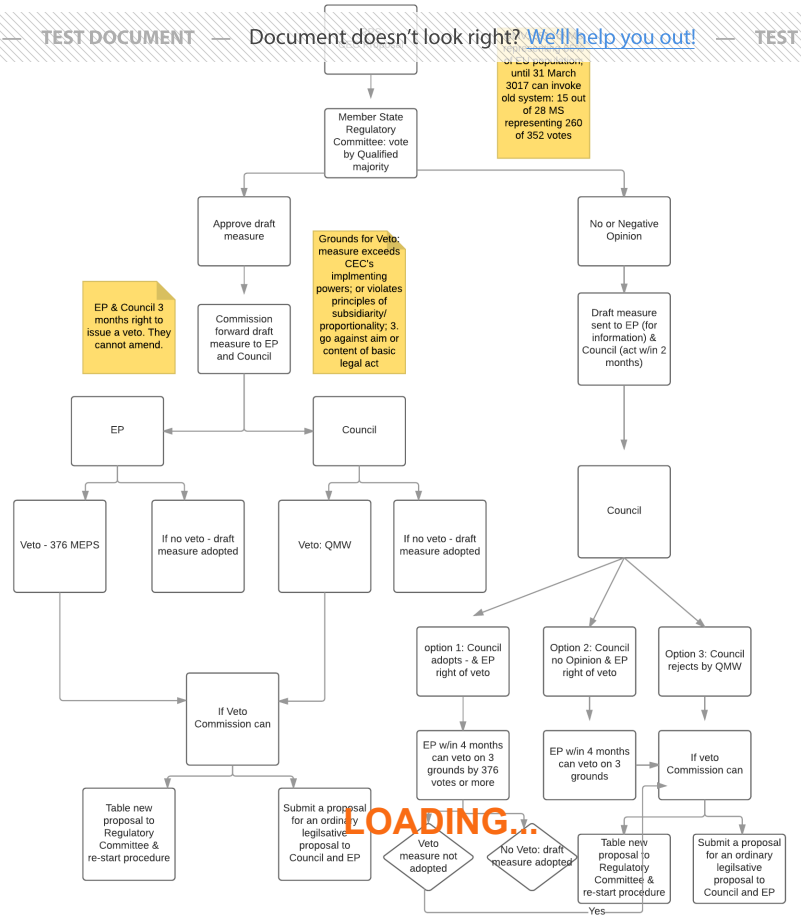
Process in Charts and Case Studies

You will find below process charts for all three processes.

I have written before on how the European Parliament has exercised their right of scrutiny for delegated legislation (see here). The European Parliament appear to be most diligent in exercising their right of scrutiny in 2016.

I will also supplement this with case studies of when Member States have successfully challenged the Commission.

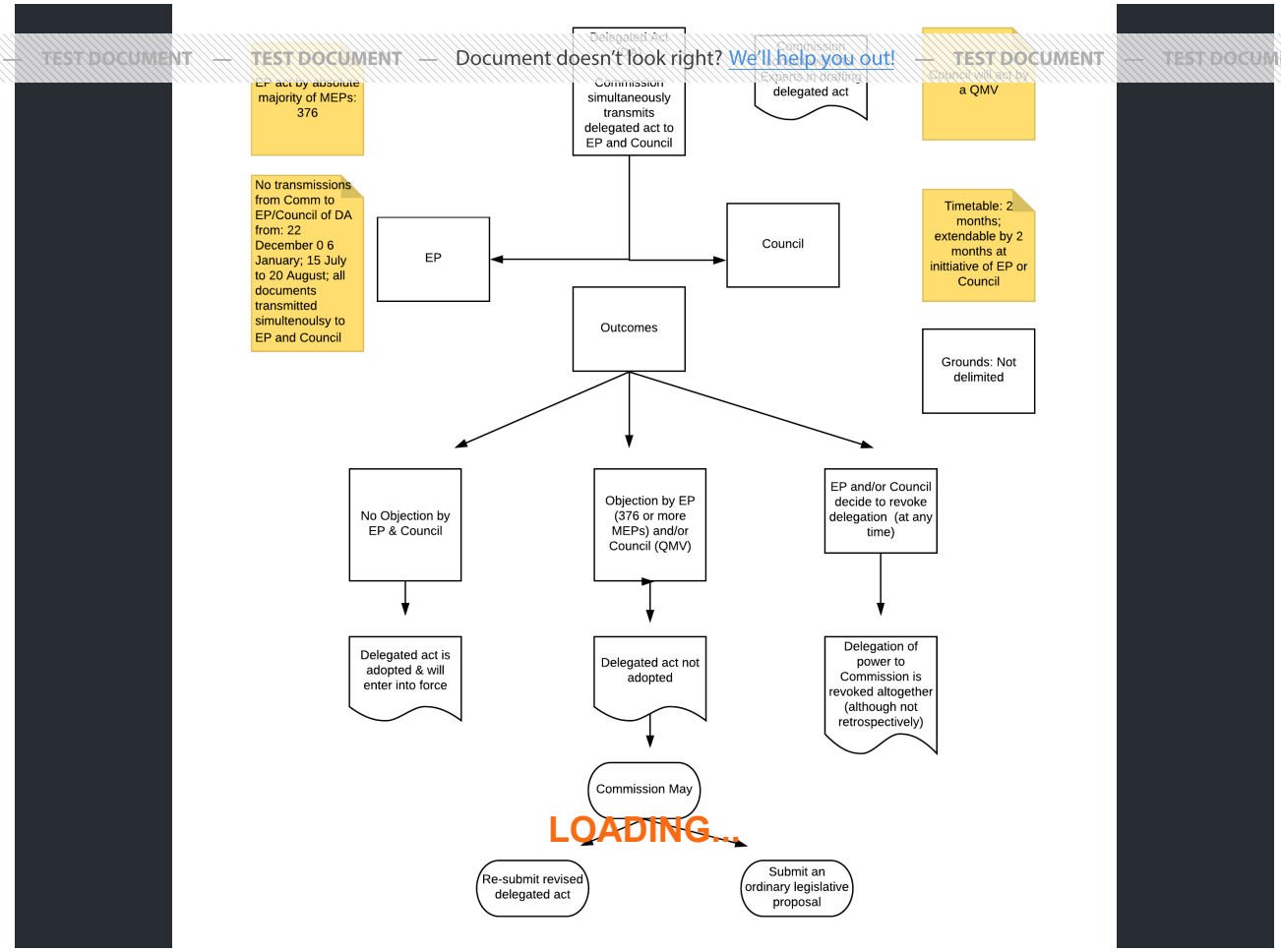
RPS



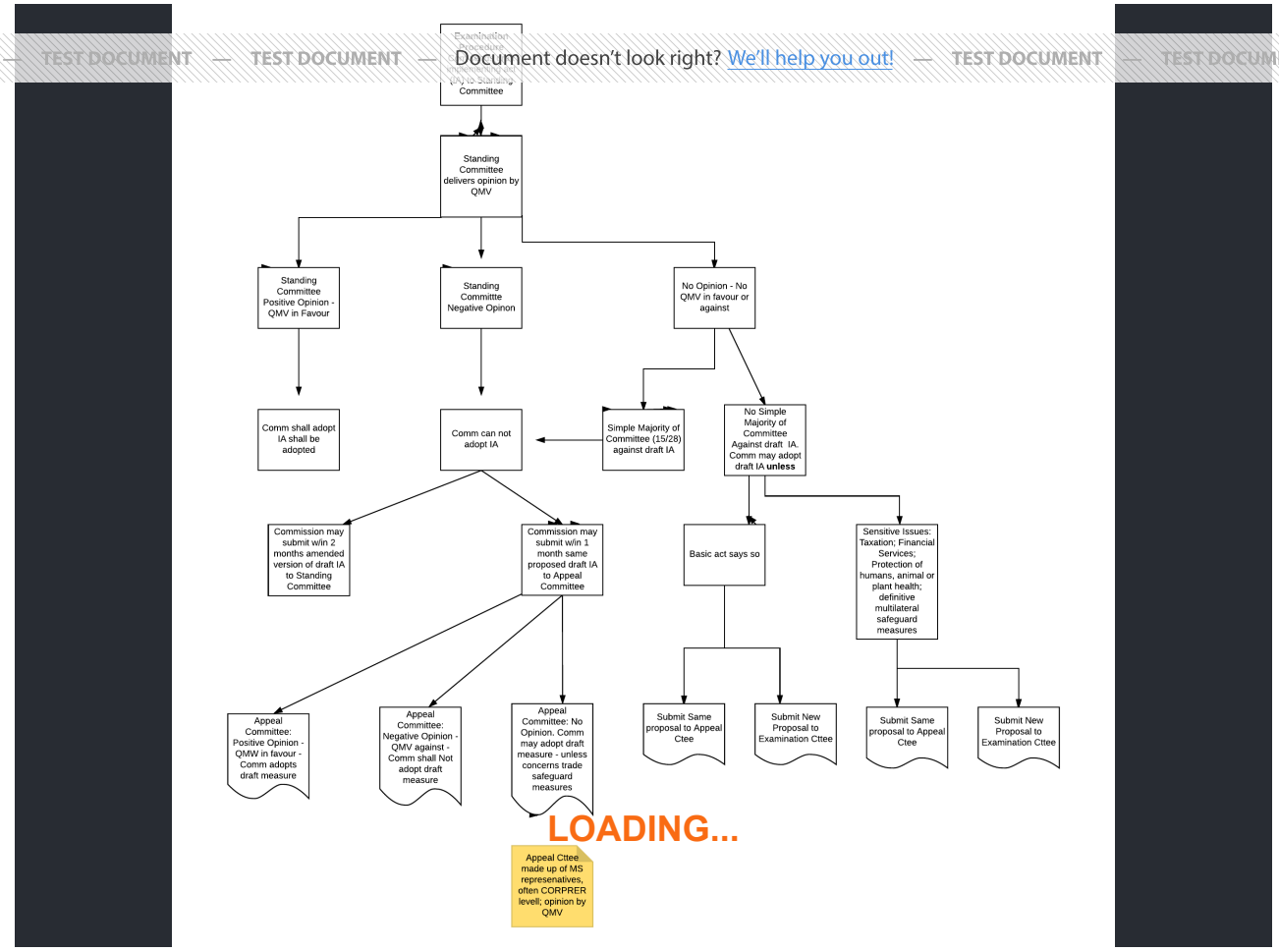
Case Study Insert by MS

Delegated Act

Process chart



See Case Study by MS.
Implementing Act



Case Study by Member State.

What if No Opinion

The challenge comes if the Standing Committee can not secure a Qualified Majority Vote for or against the draft implementing act. Sometimes, in particular on sensitive issues, like GMOs or pesticides, there is a 'No-Opinion' result.

It is clear that the Commission consider that they have a considerable margin of discretion for the Commission on what to do if there is a 'no opinion' or a 'negative opinion'.

It is important to realise that going to the Appeal Committee should be seen as an exception to the general rule. Indeed, there is no obligation on the Commission to go to the Appeal Committee. Instead, the Commission will prefer to submit an amended proposal to the Standing Committee than proceed to the Appeal Committee.

There does not appear to be a time limit on how long the Commission can find a draft that is acceptable to the committee. But, if the Commission go to the Appeal Committee and they reach no agreement in two months, no opinion is deemed to be agreed.

Exceptionally, if the draft goes to the Appeal Committee the Commission Chair has a wide margin for negotiation. Until the Appeal Committee delivers an opinion, any member state can suggest amendments and the Commission can present any amendments to the draft.
Interestingy, whilst the Appeal Committee delivers their result by QMV, the Commission do not have call a formal vote. Rather, the Commission can determine that the Committee has come to a positive opinion by consensus. A Member State can object to this.
If the Appeal Committee come to a "negative opinion", the Commission can not adopt the draft implementing act. But, if the Appeal Committee come to "no opinion" the Commission "may"adopt. It is clear that the Commission do not have to adopt the draft implementing act. Indeed on sensitive issues, there appears to be a rule of practice not to adopt it. Instead, rather than forcing the issue, the rule of practice is to seek a "consensus" at the Examination Committee phase.

Ordinary Legislation

You'll see that if the Commission is blocked it can either re-table an amended proposal or bring forward an ordinary legislative proposal.

Many people seem to fear the latter option. But, sometimes it is the only way to remedy the situation. If the original legislation has, in your view, built in defects, the only way to remedy those defects is to get the Commmission to acknowledge this and for them to table an ordinary legislative proposal.

If the Commission don't want to re-open the original law, you can force them to the table if the EP or Council block their proposed measure.

It is important to note that delegated legislation is singularly curtailed in the changes it can make. It can not be used to remedy "essential elements" of the parent legislation. The only way to remedy built in defects in the parent legislation is through a new piece of legislation introduced by way of the ordinary legislative process.

European Court of Justice

Even if the Commission gets their delegated proposal adopted, there is the possibility that a Member State (or Norway), the European Parliament, or the Council could go to European Court of Justice to quash the adopted measure.

This has happened. In Case 14/06, the Commission granted an exemption for Deca-BDE under the RoHS Directive. Denmark and others challenged the granting of the exemption. The European Court ruled that "it is sufficient to state that the contested decision, which is equivalent to a general exemption for the use of DecaBDE in electrical and electronic equipment, was adopted when the conditions laid down by the Community legislature in Article 5(1) of Directive 2002/95 had not been met and runs counter to the objective pursued by that legislature of establishing the principle of the prohibition of the components referred to in that directive." The exemption was revoked.

This is a final option when all other pathways have been closed.

How to control the European Commission when law making – Delegated legislation – Part 1

14th March 2016
EU

"Who will guard against the Guardians". Juvenal.

Most EU legislation is delegated legislation. Around 93% (and perhaps more) of EU law adopted each year is delegated legislation. The remaining is ordinary (co-decision) legislation, where most NGOs and trade associations spend most of their time and resources, often with marginal substantive impact. Most NGOs and trade associations ignore delegated legislation because they think it is either too complicated or unimportant. I think they are wrong on both counts.

When Member States and the European Parliament hand to the European Commission, through enabling legislation, the power to bring forward new secondary laws, they are handing over considerable power. It would appear that many Member States woke up very late in the day to how much power they had handed over to the European Commission under the Lisbon Treaty (2009), and realised how little control they had to amend or block Commission delegated legislation proposals. At the time, the European Parliament only seemed to be concerned with being on the same footing as the Council, and did not seem to care that they were standing on quicksand.

Today, the Member States and the European Parliament power to control European Commission exercise of delegated power is limited.

More importantly, at the moment, given the relative secrecy in which these proposals are made and adopted, the public's right to comment and participate is even more limited. However, important changes are happening by way of the Better Regulation reform in 2016 that will make delegated law making more open. The changes will also introduce more checks and balances on the Commission.

In this blog, I will cover in two parts, and in broad brush strokes:

1. The current types of delegated legislation in the EU and 3 systems for their adoption
2. How the Commission is (or is not) controlled by the European Parliament, Member States and the public

In a follow up blog, I will give some case studies that, I think, show how difficult it to stop a Commission proposal once it is made, and to update the blog in light of the new Better Regulation agreement and the Commission's self-commitments that impact delegated legislation.

Further Reading

For those interested, I'd recommend the following further reading:

- IEEP, The New Comitology Rules: Delegated and implementing acts, May 2011
- Carl Fredrik Bergstrom's 'Comitology: Delegation of Powers in the European Union and the Committee System' (2005) an excellent historical perspective and insights from some leading experts.
- Daniel Guegen, 'Comitology: Hijacking European Power?' which I am prone to hand over as a present to people who are facing the labyrinth of delegated legislation. for the first time.
- Daniel Guegen and Vicky Marrissen's Handbook on EU secondary legislation (2014)
- Daniel Guegen, who I regard as the Godfather of comitology, also publishes a comitology newsletter and provides a good training course on the system.

This law making procedure has been around for a long time, and it was often known by the term "comitology", or decision making by committee. Since the Lisbon Treaty in 2009 there was an attempt to streamline and simplify the process.

The EP has provided a useful summary here.

Today, delegated legislation there are three systems for the adoption of delegated legislation. They are:

1. Delegated acts
2. Implementing acts, or
3. Regulatory Procedure with Scrutiny.

The Lisbon Treaty only refers to delegated acts (Article 290) and implementing acts (Article 291). But, around 300 Directives exist that use the pre-2009 system and so the Regulatory Procedure with Scrutiny (RPS) system remains. The RPS is due to be phased out in 2017, but it's end has been on the cards since 2010.

Member States and the European Parliament oversee the following types of acts/measures:

- Delegated acts: resulting from legal acts adopted after the entry into force of the Lisbon Treaty (article 290);
- Implementing acts: resulting from legal acts adopted after the entry into force of the Lisbon Treaty (Article 291)
- Measures falling under the Regulatory Procedure with Scrutiny (RPS): resulting from legislative acts adopted before the entry into force of the Treaty, but which are not yet aligned.

In this blog I focus on the Parliament as they have, to date, been the most active branch of the legislature, in challenging the use (or abuse) of delegated power.

Not Avoiding Political Choices

First, it is important to realise that the Parliament and Council are making a political choice when the decide or not to delegate rule making powers to the Commission. It comes down to whether the, in particular for the Parliament, whether they have a future say in any future specific measure (delegated acts) or not (implementing measure).

Second, much to the surprise of many in Brussels, there are core limits to what can be delegated. The Parliament and Council can not delegate "essential elements". This means if the measure concerns an essential emolument it can only be dealt with in the ordinary legislation and that power to introduce measures can not be delegated.

The Court of Justice has given their opinion on what an "essential element" means. In the German Sheep meat case the Court rules that : "rules which (…) are essential to the subject-matter envisaged" and "which are intended to give concrete shape to the fundamental guidelines of Community policy." "[R]ules being merely of an implementing nature may be delegated to the Commission" (Judgment of 27 October 1992, C-240/90, Germany v Commission, paragraphs 36 and 37).

The Court developed their thinking and clarified that essential elements of a basic are those that "entail political choices falling within the responsibilities of the European Union legislature, [by requiring] the conflicting interests at issue to be weighed up on the basis of a number of assessments"(Judgment of 5 September 2012, Case C-355/10, European Parliament v. Council, paragraphs 63, 76 to 78).

This is important because this prevents the EU legislature avoiding taking hard policy choices. They Parliament and Council can not avoid taking political choices by asking the Commission to settle them for them via delegated legislation. This is in marked contrast to the US, where, at least in the field of air quality regulation, the Congress finds itself unable to make tough political choices of what air pollutant limits should be, and delegates to the US EPA those choices. Fortunately, in Europe, we avoid that abdication of political responsibility.

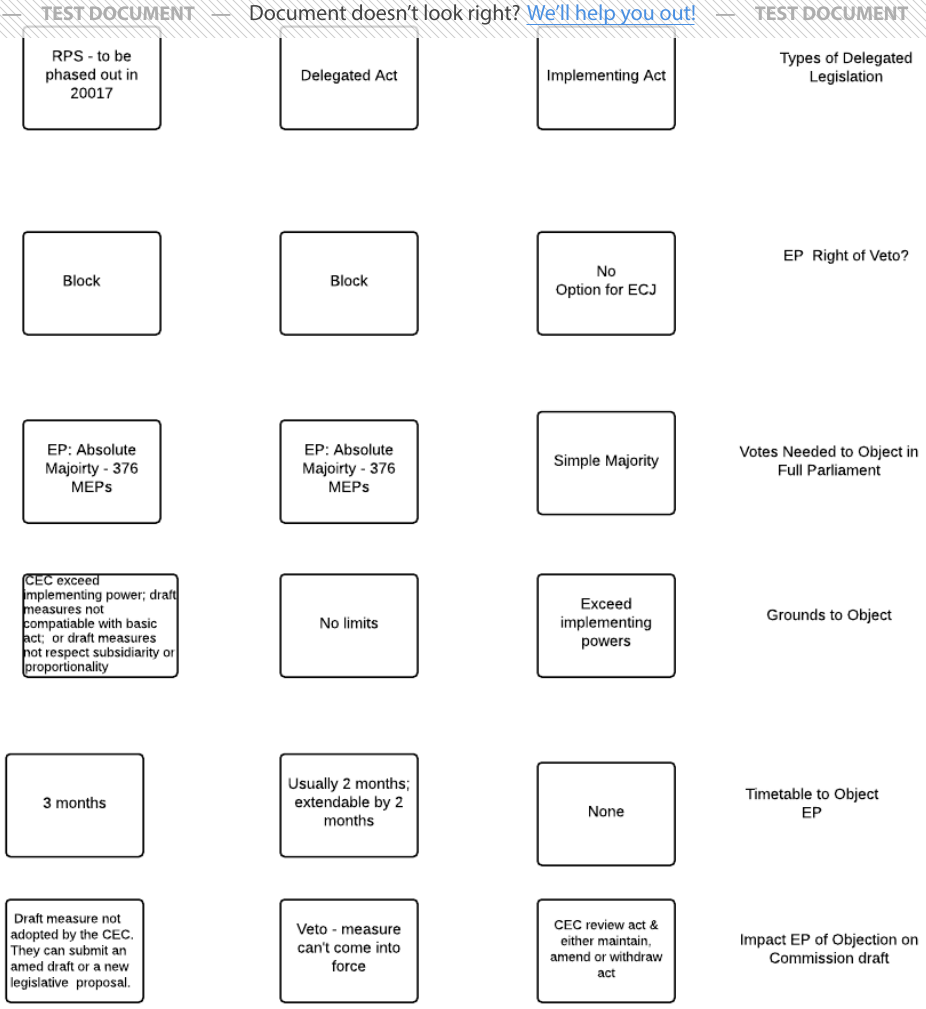
A summary of the grounds to object, timing, majorities in the EP and consequences of objection is below.

1. **Article 290 – Delegated Acts**

As the EP state "Delegated acts are used to change or supplement existing legislation. They are a way for Parliament and the Council to authorise the European Commission to revise non-essential parts of legislation, for example by adding an annex. However, Parliament and Council cannot delegate their legislative powers to the Commission to change essential parts of legislative acts.

If Parliament and the Council do not agree with the Commission's subsequent proposal, they can veto it."

The Parliament usually have 2 months with the possibility to ask for an extension for another 2 months. For environment measures, the Environment Committee send a monthly newsletter for both draft delegated, RPS, and implementing acts. A



MEP needs to email the Environment Committee Chair and Secretariat of the intention to object. If the Committee backs the objection (by simple majority) the matter is usually tabled for a vote at the next plenary session of the Parliament. At the plenary, the high hurdle of 376, an absolute majority, is set to block a draft measure.

An example of a successful challenge to a proposed delegated act is the European Parliament's successful challenge is on 12 March 2014 to the Commission's proposed measure on the definition of 'engineered nano materials in food (see here). The Parliament's challenge was adopted by 402 votes to 163 with 126 abstentions and the Commission's proposal was defeated.

Article 290

1. A legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act.

The objectives, content, scope and duration of the delegation of power shall be explicitly defined in the legislative acts. The essential elements of an area shall be reserved for the legislative act and accordingly shall not be the subject of a delegation of power.

2. Legislative acts shall explicitly lay down the conditions to which the delegation is subject; these conditions may be as follows:

(a) the European Parliament or the Council may decide to revoke the delegation;

(b) the delegated act may enter into force only if no objection has been expressed by the European Parliament or the Council within a period set by the legislative act.

For the purposes of (a) and (b), the European Parliament shall act by a majority of its component members, and the Council by a qualified majority.

3. The adjective 'delegated' shall be inserted in the title of delegated acts.

2. Article 291 – Implementing Acts

As the EP write "Implementing acts describe how legislative acts should be implemented. They are normally prepared by the Commission, which consults committees made up of representatives from EU countries.

MEPs can object to an implementing act. Although the Commission must then consider Parliament's position, it is not bound by it.".

Article 291

1. Member States shall adopt all measures of national law necessary to implement legally binding Union acts.

2. Where uniform conditions for implementing legally binding Union acts are needed, those acts shall confer implementing powers on the Commission, or, in duly justified specific cases and in the cases provided for in Articles 24 and 26 of the Treaty on European Union, on the Council.

3. For the purposes of paragraph 2, the European Parliament and the Council, acting by means of regulations in accordance with the ordinary legislative procedure, shall lay down in advance the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

4. The word 'implementing' shall be inserted in the title of implementing acts.

An example of a challenge to an implementing act is Authorisation of GM maize 1507 for cultivation (see here). The vote on 16 January 2014 was carried with 385 in favour, 201 against, and 30 abstentions. The Commission ignored the European Parliament.

3. Regulatory Procedure with Scrutiny

The EP state "This is a defunct comitology procedure that operated between 2006 and 2009 for "**quasi-legislative measures**. It can no longer be used in new legislation but appears in more than 300 existing legal acts and will **temporarily continue to apply** in these acts until they are formally amended. This procedure empowers the European Parliament and EU Council **to block a measure proposed by the Commission** if it:

- exceeds the Commission's implementing powers,
- is not compatible with the aim or content of the legal act, or
- exceeds the EU's powers or remit (see subsidiarity External Link and proportionality External Link)."

RPS is used extensively in the environment field. Around 300 directives use the procedure. The Commission is due to table a omnibus [illegible] to update all the RPS into delegated acts for 2006. That said talk about the demise of RPS has been on the table since 2010.

An example of a successful challenge to a RPS measure is Parliament's challenge to criteria for End-of-waste of paper waste (see here). This vote on 4th December 2012 was adopted with 606 for, 77 against and 10 abstentions.

How often used

It is estimated that around 93% of EU laws adopted each year are delegated legislation.

In the last European Parliament, the 7th legislative term (14 July 2009 to 30 June 2014), the European Commission tabled 584 co-decision/ordinary legislative proposals, and 488 files were adopted by the co-legilsators (the European Parliament and Council).

Over time, the trend for more co-decision proposals has grown. See below: (Source: Activity Report on Codecision and Conciliation, page.4.)

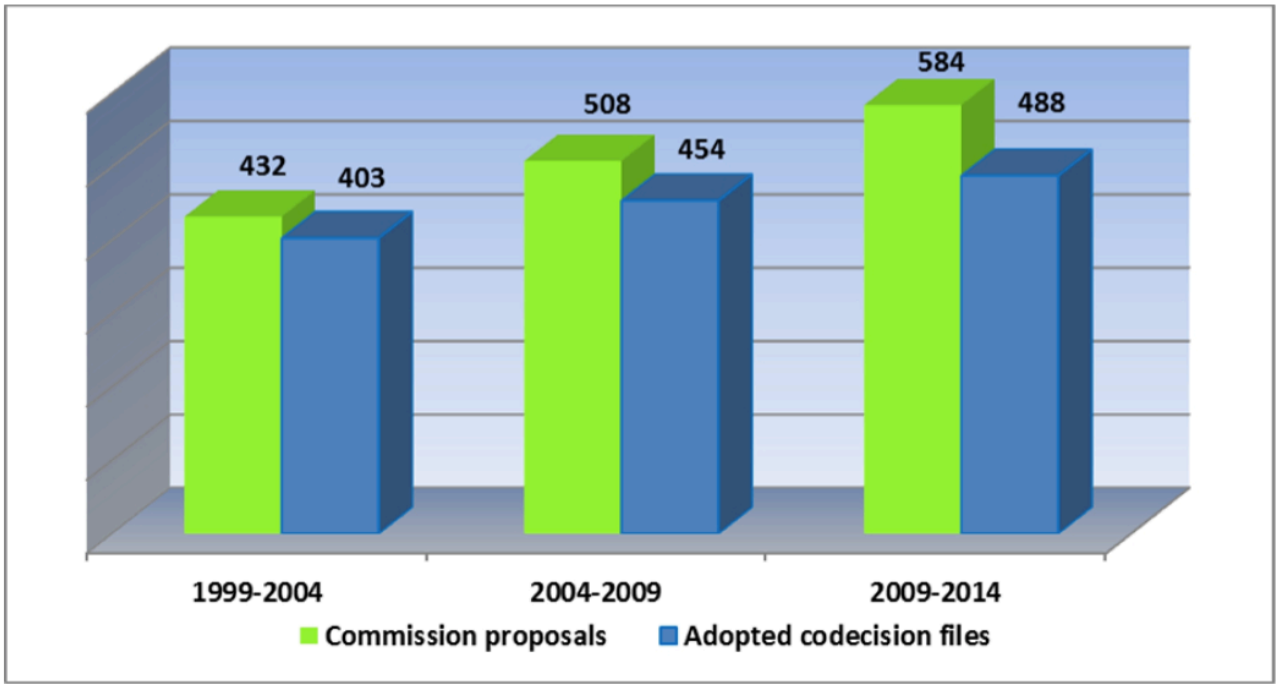


Figure 2: *Number of Commission proposals and adopted codecision files per legislative term between 1999 and 2014, based on date of adoption*[7]

But, the adoption of proposed delegated legislation is far higher. The same Parliament report provides the following chart (page 24) on the growing volume of delegated legislation that has been sent to the Parliament.

93% (or even 97%) of EU law passed each year

The European Commission in their "Report on the Working of the Committees during 2014" note that 1 899 Opinions were adopted, 1 563 Implementing Acts were adopted, and 165 RPS measures were adopted (see page 7).

By that measure, the ordinary (co-decision) legislation represents around 3% of the overall legislative workload of the EU.

Caveat
I will update this section when I can identify the correct number of pieces of delegated legislation (delegated, regulatory procedure with scrutiny, and implementing acts) sent each year to the Parliament and Council and adopted. This is an obvious discrepancy between the information from the EP and the Commission.
I focus on the work of the Environment Committee. I do so because this is the Committee I am most experienced. Also, they legislate more than other Committee in the European Parliament, and have been more for longer than any other Committee for some time. Also, they have more experience of scrutinising delegated legislation than other Committee and the most successful track record, to date, of holding the Commission and their proposals to account.

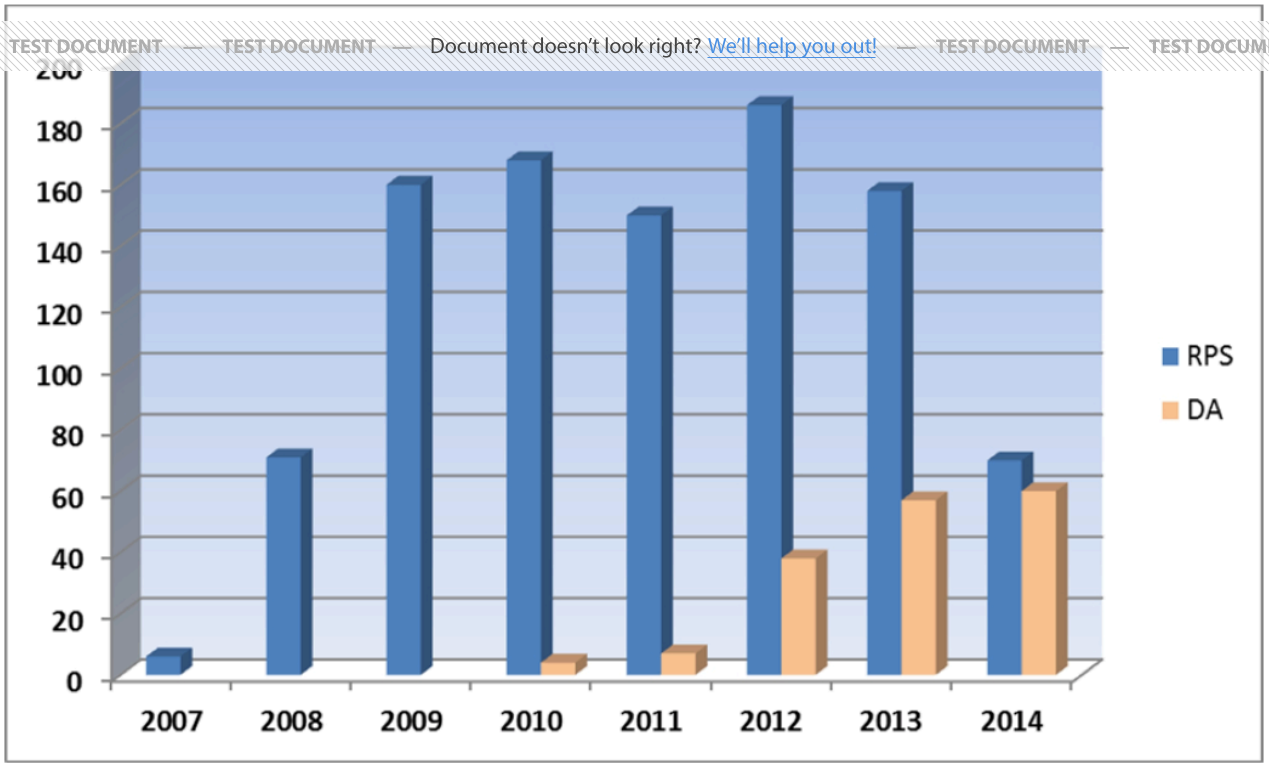


Figure 12: *Final draft RPS measures and delegated acts (DA) submitted to Parliament per year*

More Examples of Delegated Legislation

Today, delegated legislation is either an delegated act or an implementing act. It will be clear from the legal text.

The European Parliament have provided three recent examples where the European Parliament sought to control Commission delegated legislative proposals:

"MEPs vetoed a delegated act concerning suger in baby food in January, as they fear the allowed limits are too high.

In February MEPs decided against vetoing a delegated act proposing to temporarily raise NOx emission limits for diesel cars after the Commission promised to include a review clause.

Also in February MEPs objected to implementing acts approving three types of genetically modified soybeans as they were concerned the soybeans could contain traces of a herbicide that was classified as "probably carcinogenic".

The main consequence is that the Parliament or Council (or both) will find it far easier to veto a delegated act. The Commission has not withdrawn any implementing act measure the Parliament has objected to.

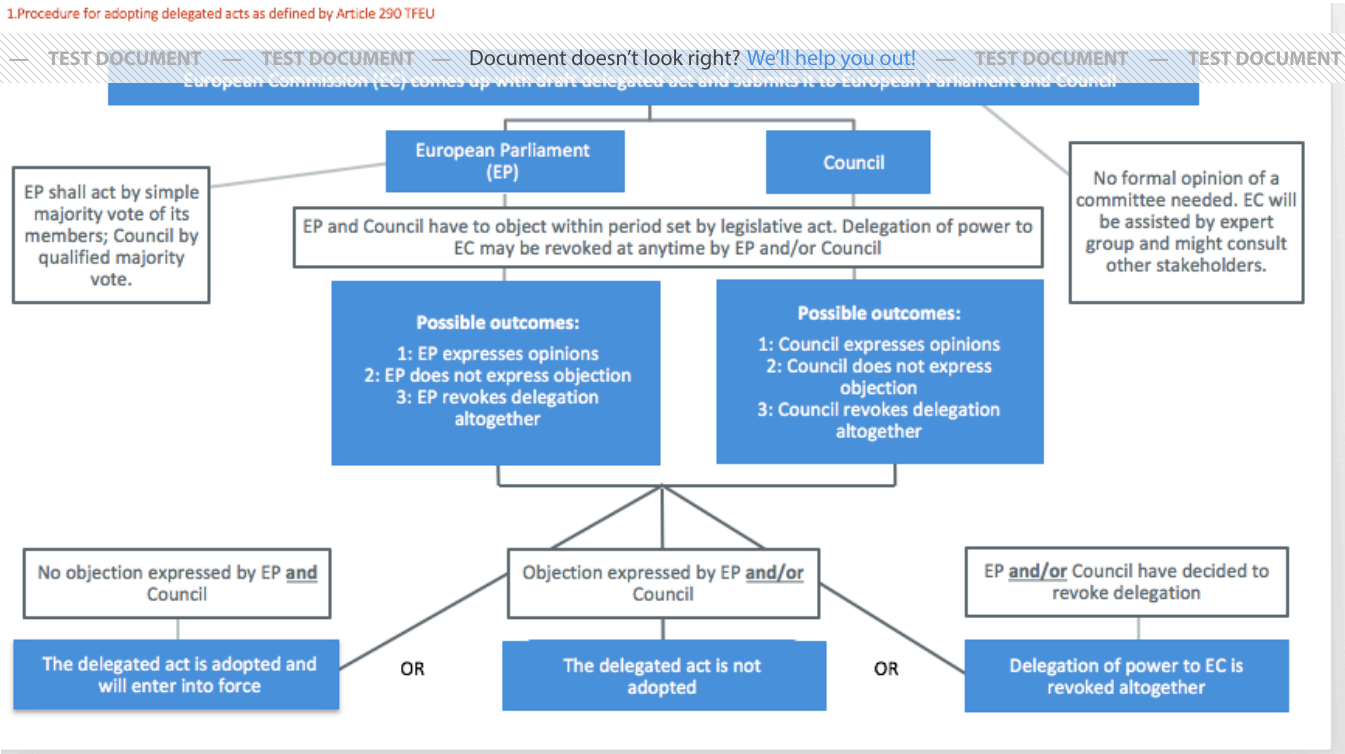
The Process in Charts

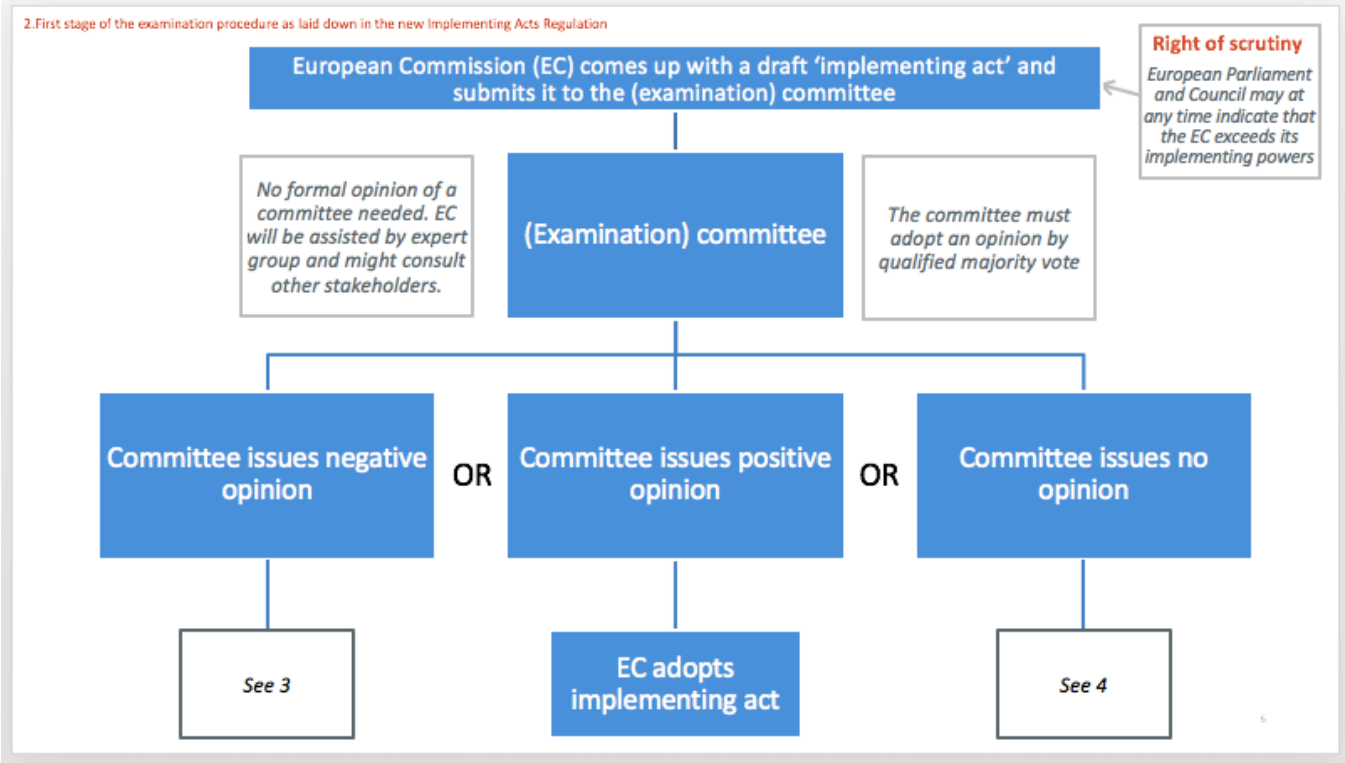
The IEEP have produced an excellent guide on the existing system which you can find here. The charts below are derived from that study and provide a useful schematic of the current system. These charts are helpful high level maps of the pathway to travel, but they are not detailed travel plans, which are individual for each journey.

1. **Delegated Acts**

2. Implementing Acts

3. Regulatory Procedure with Scrutiny





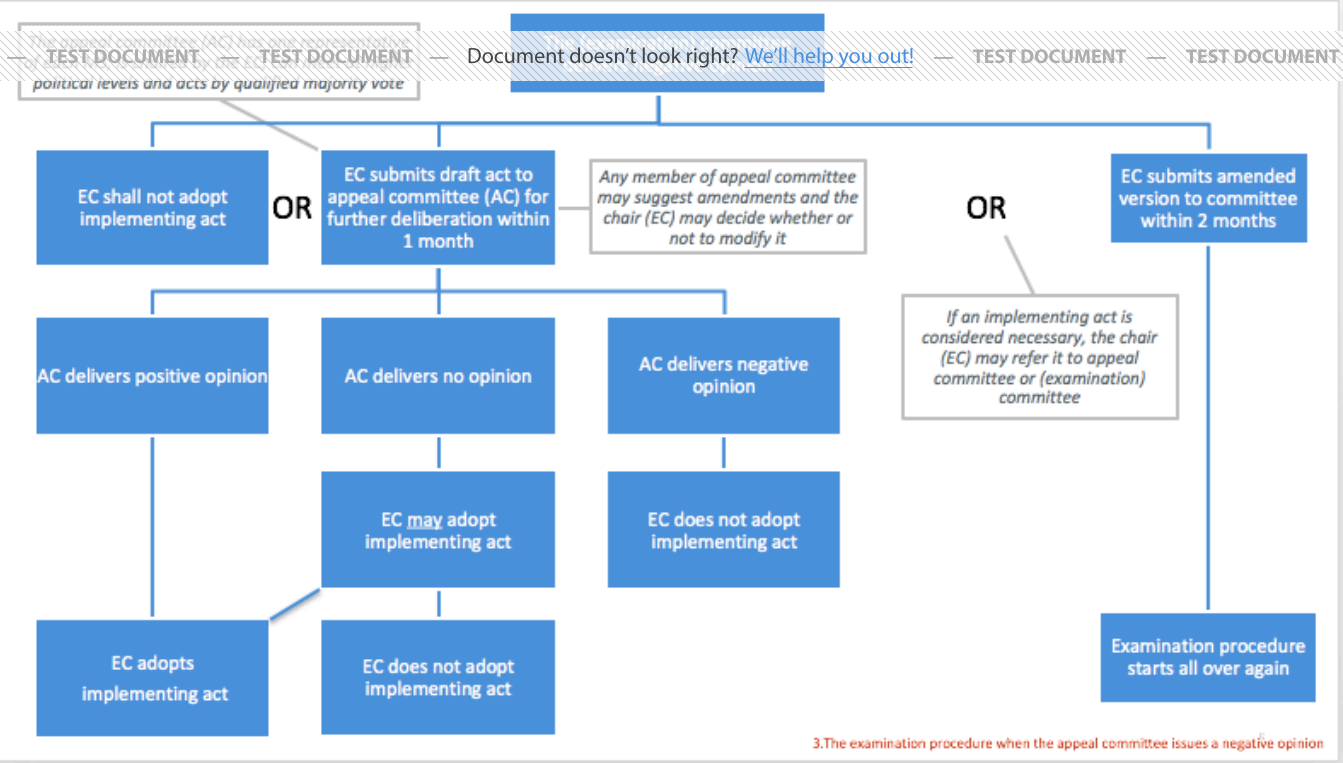
Tracking the Proposals

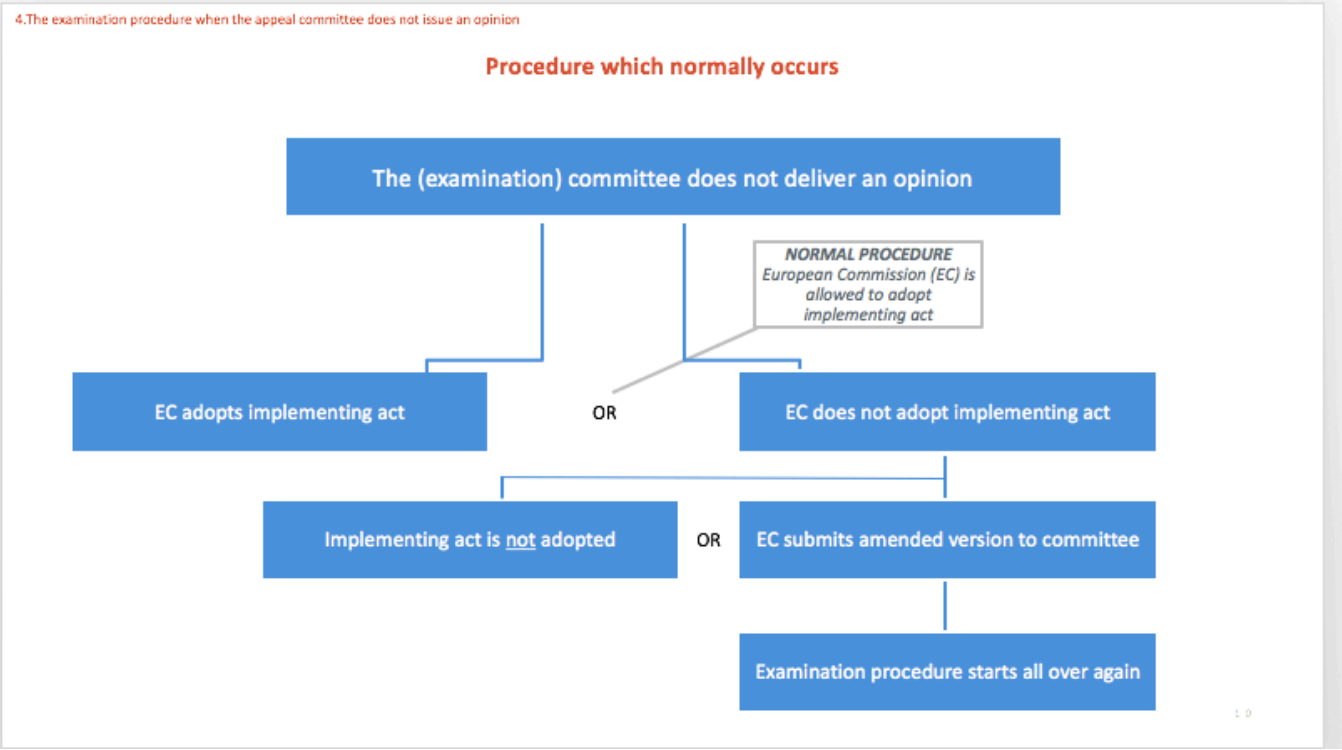
Public

For the public, there is no public source of draft measures prepared by the Commission that the public can examine. Unlike ordinary legislation, where you can look up proposals and where they are via EUR-lex there is no similar database for delegated legislation.

You can embark on a journey of discovery and search the Commission's comitology database for proposed implementing acts and RPS measures. But so poor is it's ease of use that asking a recently experienced cyber hacker would be advisable.

And, if the Commission forget to transfer the documents to the Parliament, you'll still be none the wiser as to what proposals



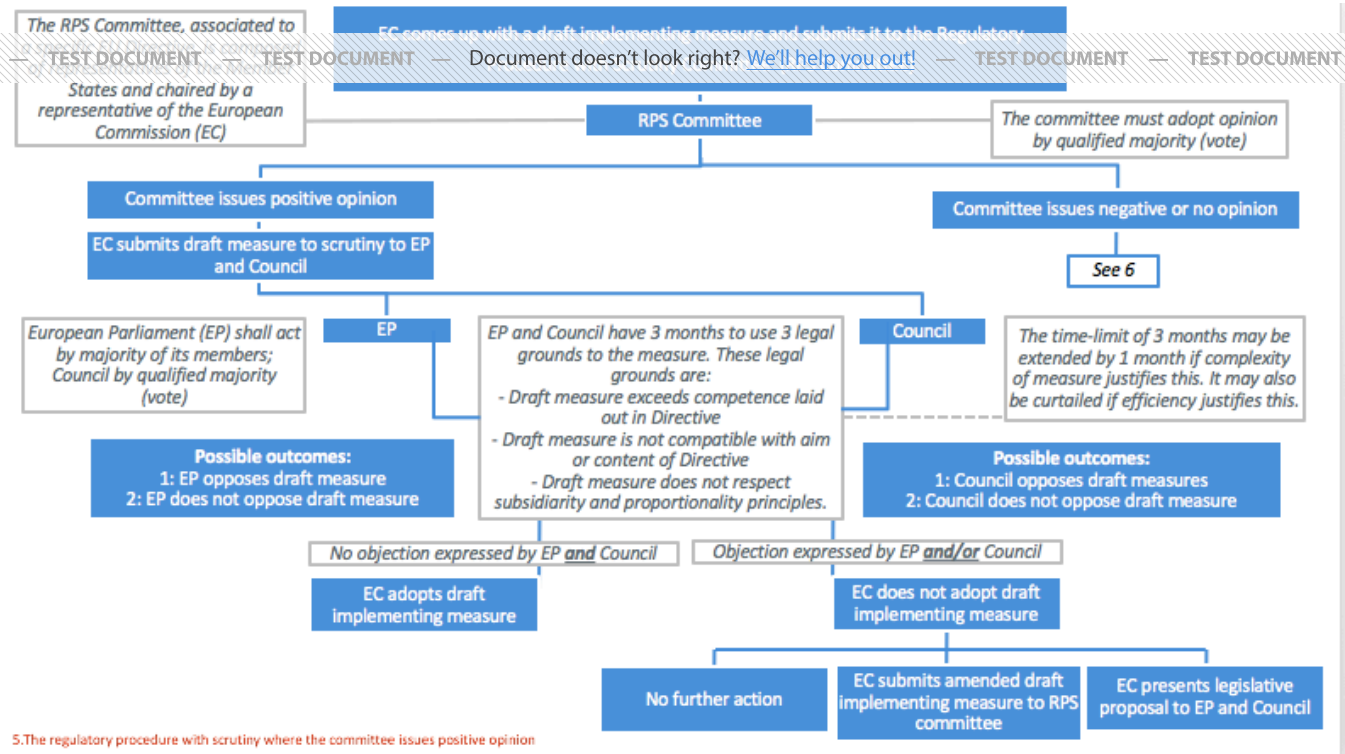


are lurking around.

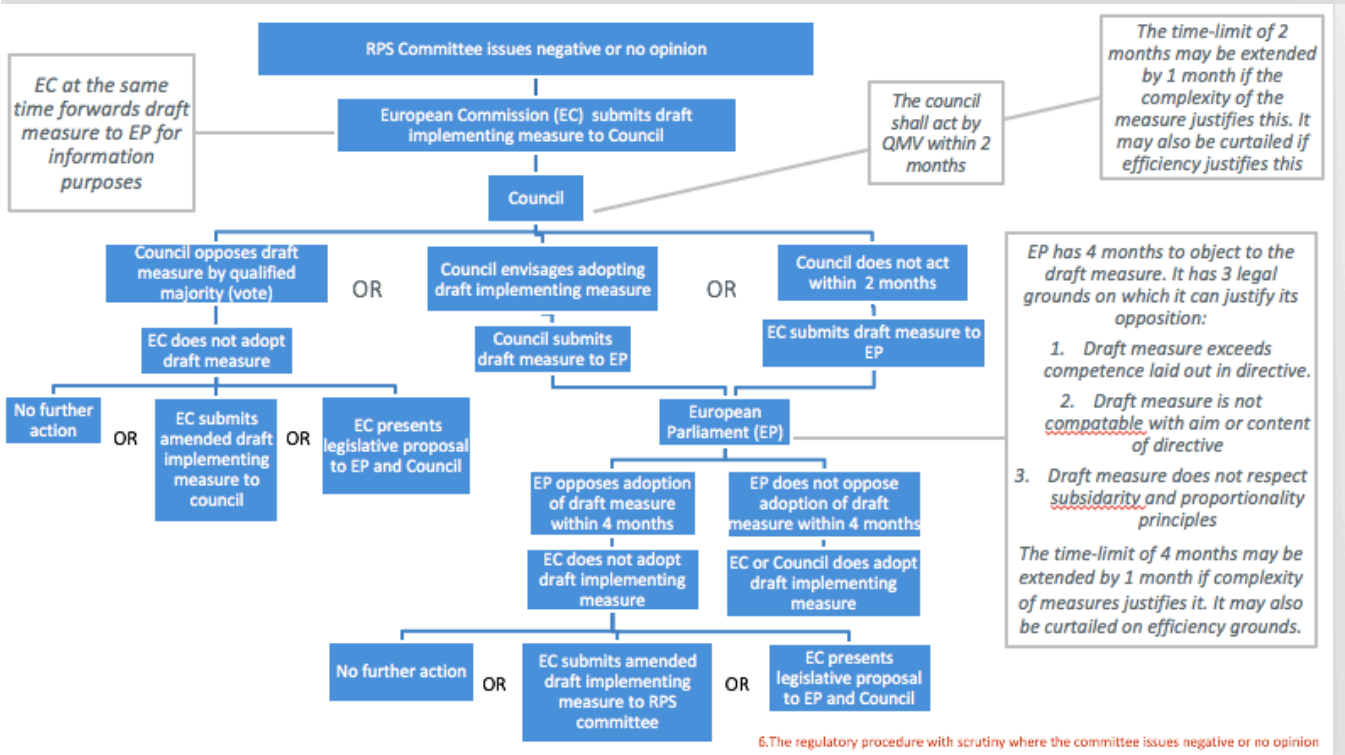
Fortunately, the EFTA States in February 2016 launched their own database of EU delegated legislative proposals. As the EFTA agreement does not cover all areas, such as fisheries, it covers most, but not all, proposals. It is a very clear database.

European Parliament and Council

Today the Commission notify the Member States and the European Parliament of their proposals via a functional email box



5.The regulatory procedure with scrutiny where the committee issues positive opinion



6.The regulatory procedure with scrutiny where the committee issues negative or no opinion

The functional email box has limitations. Whilst many of the measures are technical, some are sensitive, and sometimes the Commission Services have shown themselves unable to operate the system. The system operates on a basis of trust with the Commission sending the correct files to the Council and the Parliament by way of functional email boxes. Sometimes the Commission have not done this.

For example, as recently as December 2014, the Environment Committee started an objection to a "delegated act entitled Commission delegated Regulation (EU) No …/..of of 12.12.2013 amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers as regards the definition of 'engineered nanomaterials'. The delegated Regulation adapts the existing definition of 'engineered nanomaterials' in Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers as regards the definition of 'engineered nanomaterials' which was recently adopted by the Commission on its revised 2011."

The objection from the Parliament centred on (1) substantive and (2) procedural grounds. In this case, the European Commission published the act before the period of objection from the Parliament or Council had expired. The Commission acknowledged their error, citing a clerical error and a high volumes of procedures out, whilst the act was published on 19 December 2014, the error was spotted, and a notice published in the Official Journal that the notice of 19 December was null and void. The Parliament were notified on 19 December of the error.

This case is not isolated. In 2000, the Environment Committee stumbled upon the systematic non-transmission of proposals from the Commission to the European Parliament for many proposals across a few Commission departments.

That said, sometimes delays have happened inside the European Parliament re-allocating the dossier to the correct Parliamentary Committee.

Leaks

Today, this does not mean the draft measures do not leak. Well sourced interests will gain access to the documents, but the public won't. The European Parliament in practice is left to being informed by well informed "observers" about "problematic proposals" coming down the pipeline.

Impact Assessments

Delegated legislation that has a "serious impact" is meant to have an impact assessment. This is a good way members of the public to see what proposals are in the pipeline.

Measures that have a significant impact are already meant to have an accompanying road map. However, it is interesting to observe that even today many delegated legislative proposals the Commission put forward, that have significant first order, let alone second or third order impacts, still have no Road Maps. Without the Commission Services policing themselves to flag significant impacts with their own proposals, it is unlikely that politically or economically sensitive proposals will be weeded out or flagged for political sign before adoption. And, as nearly 99% of EU delegated or implementing acts go through untouched by the influence of the Parliament or Member Stares, the only way to weed out weak proposals is the inter-service consultation phase. I'll touch on that in tomorrow's blog.

Follow Up

Tomorrow, I will look at some case studies to show how difficult it is for the Parliament and Council to challenge the Commission. In fact, I'd go so far that this power of control over the Commission verges on to hypothetical. For example, the Commission have never withdrawn an implementing act challenged by the Parliament.

Second, I'll detail how the new Better Regulation Agreement changes the mechanics of the current system (which it does for delegated acts) and how the Commission's unilateral commitments on Better Regulation and delegated legislation (public consultation on draft measures) will positively impact open law making.

How to control the Commission when law making – delegated legislation – Part 2 – The Benefits of Better Regulation

24th March 2016
EU

Better Regulation and Delegated Legislation

On the expectation that few people (in or outside the Commission) read the rules about how the Commission operate and prepare laws (and the same rules they fortunately publish), I wanted to provide a brief summary of how the new Commission Better Regulation rules impact delegated legislation.

The Commission has two sets of commitments on Better Regulation that need to be read in conjunction with each other. First, there is the Inter-Institutional Agreement, and second there are the Commission's self commitments are laid out in two documents:

- The Better Regulation Guidelines (here)
- Better Regulation "Toolbox" (here)

These commitments will apply in addition to the Inter-Institutional Agreement. I have written on some of those changes on the Agreement here.

The self commitments are worth reading as an unusual example of clear and coherent drafting from the Commission services. One can only hope that lucidity of the Guidelines and the Toolbox are such that Commission officials can not say they did understand the new rules, and use ignorance as a reason for not applying thm.

Taken together, the new rules will, if the Commission can apply them on the Services, be positive for open and better law making overall. And, for delegated legislation they will be a radical and welcome move to bring the EU into the sunshine of the 21st century.

Reason for these changes

They have come about for two main reasons.

First, Vice-President Timmermans made explicit personal commitments to overhaul the Commission's delegated law making process in his confirmation hearings.

Second, as ENDS reported on 21 March 2016, it is a by-product of the EU-US talks under TTIP. The US system of law making is more transparent than the EU system, and the EU have opted to drag the EU system into the light of the 21st century.

The challenge will be for the Commission Services to respect these guidelines. After so long drafting and passing delegated legislation with little or no political oversight from the Commissioners, their Cabinets, or the Secretary-General policing the guidelines, it will be hard to break old habits. As I have written before European Parliament and Member State scrutiny is at times theoretical, and the public seem to be a bystander to be ignored.

Policing

The Secretary-General and the Cabinet of V-P Timmerman's will be left to police these new rules. I suspect that they will be

Why these changes are helpful

It is a strange constant at how often important delegated legislative measures are pushed by some Commission Services without any consideration of President Juncker's Political Guidelines or the Commission's internal guidelines. I have been surprised to discover some Services are unaware that some delegated legislation need Impact Assessments, or that Road Maps are needed for measures for political validation rom the Commissioner. It helps explain why sometimes important draft delegated legislative proposals do not even exist in the Commission's internal database that is mean to track all legislative work. For the latter, I guess it is hard to ask questions about a proposal in inter-service consultation if it officially the draft delegated measure does not exist.

Key provisions

The self commitments are helpful in that clarifies the rules for (1) political validation, (2) public scrutiny, (3) and the use of impact assessments, and (4) road maps for delegated implementing acts.

Road Maps and Validation

For the lack of reference, the Guidelines are worth citing in full.

Box 2. Scoping, political validation and inter service work (See Page 8)

- Major initiatives must be accompanied by a Roadmap and entered into Agenda Planning as soon as preparatory work starts – at least 12 months prior to adoption by the College. They must be validated by the lead Commissioner, relevant Vice- President and the First Vice-President before being accepted to be included into the Commissions' planning. The political validation must be understood as giving the green light to proceed with further preparatory work. It should not be interpreted as a decision on a particular initiative or course of action that prejudges the outcome of any impact assessment process, stakeholder consultation or later political discussion in the College.
- Roadmaps explain what the Commission is considering. A Roadmap describes the problem to be tackled and the objectives to be achieved. It sets out why EU action may be needed and its value added. The policy options being considered are outlined. The Roadmap also justifies the absence of an impact assessment. It also announces the details of the stakeholder consultation strategy (see later chapter). A (different) Roadmap is also prepared for each evaluation and Fitness Check. This specifies the scope of the evaluation and presents the evaluation questions to be answered.
- An Inception Impact Assessment is a Roadmap for initiatives subject to an IA that sets out in greater detail the description of the problem, issues related to subsidiarity, the policy objectives and options as well as the likely impacts of each option.
- All Roadmaps and Inception Impact Assessments are published by the Secretariat General on the Commission's website8 so that stakeholders are informed and can provide initial feedback (including data and information they may possess) on all aspects of the intended initiative and impact assessment."

Evaluations, impact assessments, stakeholder consultations, policy proposals and implementation plans must be prepared collectively by the services9 within an interservice group. It is important that all services with an interest participate actively in the interservice work from the outset, particularly those DGs with specific expertise (e.g. competitiveness, SME impacts, social impacts, environmental impacts and scientific/analytical) (See Page 7 Guidelines).

Before Going Anywhere

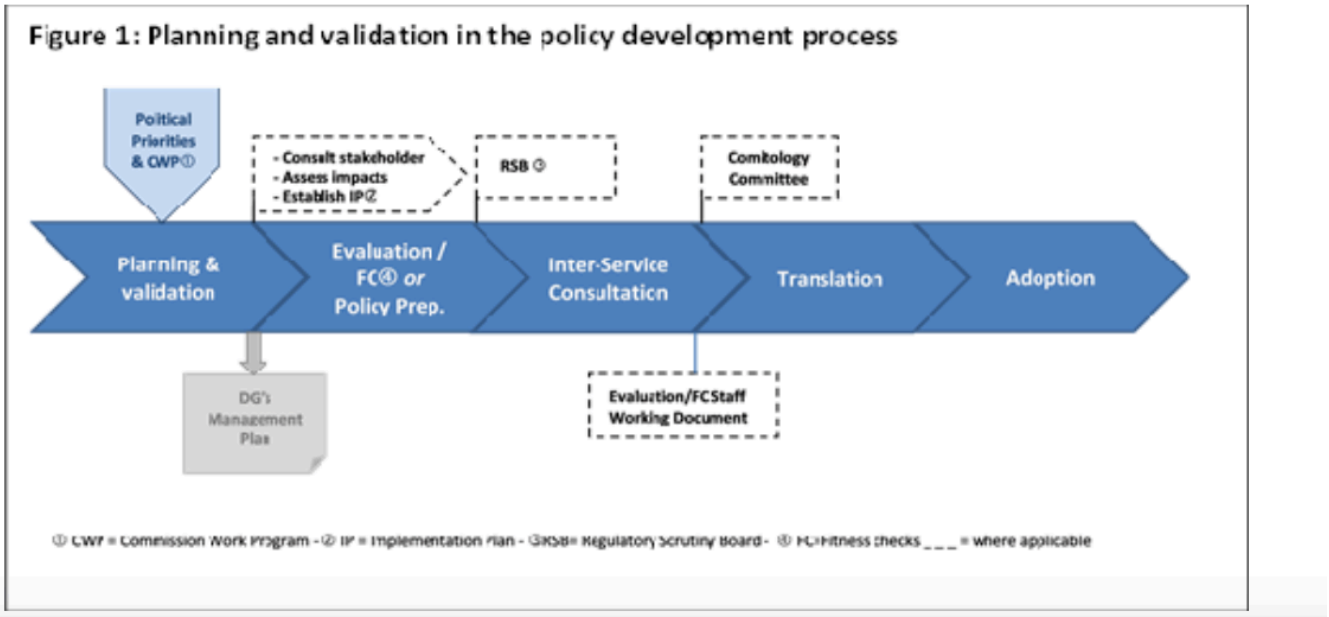
The Guidelines (page 11) make clear that no work at all can continue unless:

Key requirements

- Work may only start and the necessary resources attributed if an initiative has received political validation at the appropriate level and a valid entry exists in Agenda Planning, where applicable (cf. point 3 below).
- "Major" new initiatives have to be accompanied by a Roadmap or Inception IA and require political validation from the lead Commissioner, Vice-President and First Vice President.
- A valid agenda planning entry is needed in order to launch an interservice consultation.

This graphic is helpful in explaining the steps (See Guidelines page 11)

Work may start and the necessary resources may be attributed only if political validation has been obtained from the appropriate level.



See Page 12 Guidelines

See Guidelines page 13

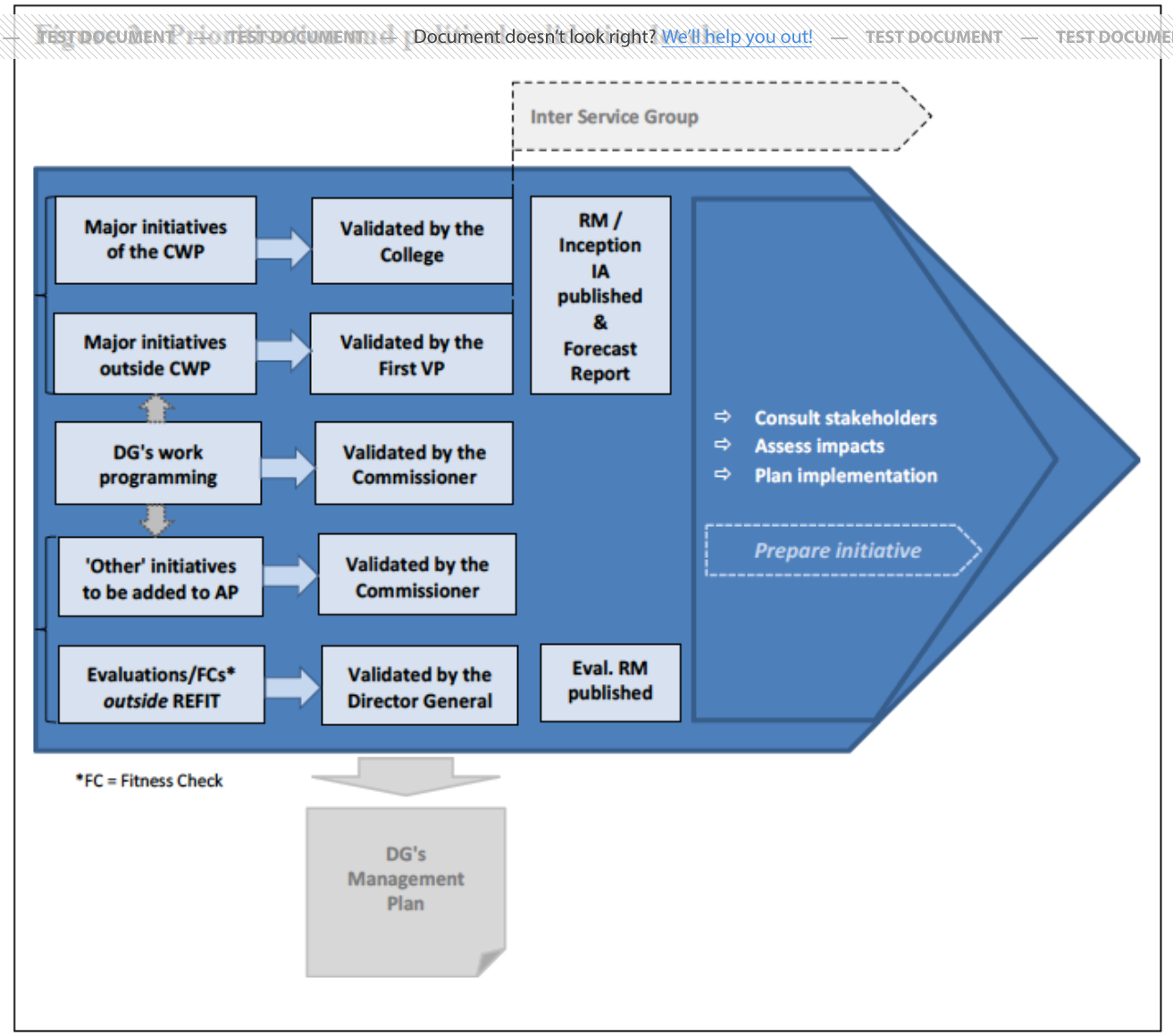
Delegated Legislation is Covered

Let's be clear, delegated legislation can be subject to "validation", and if it "has significant impact" must be.

As the Guidelines state: " All 'major initiatives' need to be entered into Agenda Planning at the latest 12 months before their planned adoption date and be accompanied by a Roadmap16 or an Inception Impact Assessment. The implementing instructions identify certain types of acts as being per definition 'major'. However, any other Commission initiative that is sensitive or important should also be considered as 'major'. It is the responsibility of each DG to consider carefully aspects such as the political importance and sensitivity, the magnitude of the expected impacts; importance for other policy areas and prior knowledge about divergent or sensitive stakeholder views (see Page 13 Guidelines)".

And, in case there is any confusion, the Guidelines provide a clear chart to make clear that delegated legislation having significant impacts require validation, and the subsequent steps that such measures needed.

See Page 14 Guidelines



Conditions to launch ISC	• Only if complete AP entry exists • If impact assessment: positive opinion of the RSB • Validation by the Commissioner(s), VP(s) and the First VP	• Only if complete AP entry exists • Validation by Commissioner(s), VP(s) and the First VP	• Validation by the Commissioner

What happens if officials don't comply with the rules?

The Guidelines helpfully spell out to Commission Services that if they don't follow the new rules the draft proposal can be blocked:

"If preparatory work for a possibly important or sensitive initiative is carried out only at internal DG level and outside of Agenda Planning, the launch of the ISC may not be validated at political level, or the initiative may be blocked by any DG at the ISC stage, due to the lack of transparency and non-compliance with the implementing instructions." (see Page 15 Guidelines) .

Public Consultation Timelines

Different initiatives and validation requirements				
Which acts?	• Initiatives included in the CWP • REFIT items • New legislative proposals • Recommendations for the negotiation of international agreements and proposals for their conclusion • Policy communications • Delegated and implementing acts having significant impacts • Financing decisions having significant impacts • Other Commission initiatives that are sensitive or important	• Delegated and implementing acts not having significant impacts • Commission reports except for Evaluations or Fitness Checks	Non-major evaluations and Fitness Checks	• Commission decisions of administrative and routine nature • Intermediate legislative acts • Implementing decisions under International Treaties • Financing decision of a routine nature • Information notes for the Commission • Decisions granting delegated powers (empowerment and delegations) • Infringement, competition and state aid cases, trade defence cases, enforcement action under international trade rules • Emergency procedures (duly justified) • Any other initiative
AP entry?	Mandatory	Mandatory	Mandatory	Not required
Roadmap/ Inception IA needed?	Mandatory, signed off by the Commissioner(s). For initiatives that will undergo impact assessment, the Roadmap should be presented in the form of an Inception IA.	Not required	Mandatory, signed off by the Director General	Not required
Political validation by	Commissioner(s), VP(s) and the First VP, in close cooperation with President's Cabinet	Commissioner	Director General through the Management Plan endorsement	Commissioner
ISG required	Yes (Important/sensitive cases chaired by SG)	No	Yes	No

The Commission will introduce on or around 1st July 2016 a public screening and consultation process for draft delegated and implementing acts. I presume that RPS measures will be included in this new database.
This means that for draft delegated and implementing acts the public will be given 4 weeks to provide feedback.

For draft delegated acts this means the 4 week public consultation will start "after conclusion of the Inter- Service-Consultation in parallel with Member State experts.

For drafting implementing acts this means the 4 weeks public consultation will commence "after conclusion of the Inter-Service-Consultation and before the vote in the Comitology Committee".

This will give the Commission a final chance to check if they have overlooked an important first order impact, or second or third order impacts.

In addition, the Commission will publish a version of their Agenda Planning on the database that lists upcoming delegated legislative measures coming on stream.

Of course, there will be exceptions to the the need for publicity. The Guideless provide a table replicated below of those

Exceptions to the 4-week public consultation on Delegated/Implementing Acts[89]:

Type	Reason	Examples
No (or limited) margin of discretion	Lack of policy alternatives	Acts implementing an international standards into EU law without any (or limited) discretion. Corrigenda
Drafts have been prepared by an EU agency or body and have been subject to full public consultation before being submitted to the Commission and for which the Commission does not have the intention to significantly modify them	Extensive consultation on the draft text has already taken place in a dedicated framework	Acts based on regulatory technical standards submitted by the European Banking Authority or by European Securities and Markets Authority
Urgency / emergency measures	Time limitations do not allow additional consultation period	Acts under the urgency procedure or other urgent acts, e.g. temporary exceptional support measures in the agricultural field, urgent/emergency measures addressing threats to public, animal or plant health.
Budgetary procedures and	Lack of policy	Decisions on work

[89] The table refers to delegated and implementing acts. This does not prejudge in any way the choice of instrument; certain types of acts such as those linked to budgetary procedures and programme management or individual authorisation decisions, can, by their nature, only be implementing acts.

See Page 67-68 Guidelines.

Timing for consultation

The Guidelines provide a timetable for the standard public consultations.

See Page 77 Guidelines.

measures, programme management decisions	alternatives / implementation of agreements already decided on	programmes and selection and award decisions
Individual authorisation decisions / acts / decisions based on the assessment of compliance with legal requirements	Lack of significant impact, routine acts	Marketing authorisations in the pharmaceutical field or comparable authorisations, inclusions, amendments in the PDO&PGI register, (de) classification of control bodies
Temporary risk management decisions	Lack of policy alternatives / no significant direct impacts / no deviation from the advice of risk assessors	Temporary food safety measures
Based on scientific opinions from an agency or scientific committee on which a public consultation has already taken place where the Commission follows the agency findings	Extensive consultation on the substance has already taken place in a dedicated framework	Areas in which agencies such as EFSA have given a scientific advise

The Guidelines are accompanied by a more detailed Toolbox. This provides 59 tools for Commission Services to use in their work and complying with Better Regulation. There will be little margin for error given how clear and comprehensive these rules are.

The Toolbox provides some helpful clarification on a number of points.

The Commission leads will have to provide a justification on why a draft delegated measure does not have a major impact. At the moment, the Services just need to tick a book saying this is the case and provide no reason or reasoning why this is so. The Toolbox states "DGs should not start work without having political validation by the responsible Commissioner. At the latest 3 months before the planned adoption, the initiative has to be introduced in Agenda Planning. For delegated acts and implementing acts an appropriate justification why they do not have significant impacts and are thus 'not major' has to be provided." (page 10 Toolbox).

In relation to risk management decisions, nuanced criteria may limit the application of some Impact Assessment rules.

Mandatory open, internet-based public consultation:	***How long?***	***When?***
• Initiatives with impact assessments • Evaluations • Fitness Checks	Minimum 12 weeks[107]	Decision on case-by-case basis
• Green Papers		After adoption by the Commission
Stakeholders must be enabled to give feedback on:	***How long?***	***When?***
• Roadmaps for Evaluations and Fitness checks	4 weeks	After publication
• Roadmaps, Inception Impact Assessments	Indication to be provided	After publication
• Draft Delegated Acts[108]	4 weeks	After conclusion of the Inter-Service-Consultation in parallel with Member State experts.
• Draft Implementing Acts[109]	4 weeks	After conclusion of the Inter-Service-Consultation and before the vote in the Comitology Committee
• Legislative or policy proposals adopted by the College and, where applicable, the accompanying impact assessments	8 weeks	After adoption by the Commission

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Strasbourg, 19.5.2015
SWD(2015) 111 final

COMMISSION STAFF WORKING DOCUMENT

Better Regulation Guidelines

{COM(2015) 215 final}
{SWD(2015) 110 final}

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EUROPEAN COMMISSION

Better Regulation "Toolbox"

This Toolbox complements the Better Regulation Guideline presented in in SWD(2015) 111

It is presented here in the form of a single document and structured around various chapters containing individual tools. It is also available and intended to be used as a series of web-tools which are downloadable from the Commission's Better Regulation web site. http://ec.europa.eu/smart-regulation/index_en.htm

br_toolbox_en

The Toolbox presents a comprehensive array of additional guidance to assist practitioners in the application of Better Regulation. Users are not expected to read and apply each individual tool but to use the toolbox selectively and with common sense.

Questions about this toolbox can be sent to units C1, C2, C3 and C4 of Directorate responsible for Smart Regulation and the Work Programme in the Secretariat General.

Some trends in Environment Committee comitology challenges

7th March 2021
Comitology

The Environment Committee has debated 45 challenges to secondary legislation. 10 failed.

If the Environment Committee backs the challenge, most of the time the full Parliament backs the challenge, usually with clear majorities.

The challenges fall into the following categories: GMOs 19, Pesticides 14, Food 6, Chemicals 5, Other 2

Some Observations

Looking at the challenges that have got backing:

- Only 'pro-environment challenges get past the Committee.
- The rhythm of the scrutiny is now familiar. The coalition of winners is well set. They are cross-party. The challenges are often are a proxy for broader issues (e.g. deforestation for GMOs) than the file suggests.
- There is a clear trend for targeted substance challenges for pesticides.
- Issues raised in the debates are clear. The debates for some challenges seem identical to previous challenges.
- The challenges are not a surprise. Anything linked to contributing to certain issues will be challenged.
- The Commission briefs MEPs. For some challenges, the Commission's points have been raised by MEPs before the Commission gets around to speaking.
- An alleged divergence between the scientific advice of an EU Agency and the proposal is a trigger for a challenge.
- Challenges are a mix of politics, law, and defending Parliamentary privileges.

What challenges did not get backing?

Looking at the challenges that did not succeed is helpful.

- Anything tabled by the ECR or ID does not pass in the Committee or plenary.
- Pro-industry challenges fail.
- The *Cordon sanitaire* for the ID is alive.
- Single MEP challenges don't tend to secure support.
- If it is not backed by the Environment Committee, and a group table the challenge to the plenary, it will fall.

Broader Observations

If you listen to the challenges you will learn they are about broader political issues. GMO challenges are about deforestation in the Amazon.

It is useful to listen to the issues that are driving the concerns of MEPs.

It is clear that any substance that can be suggested as an endocrine disruptor or carcinogenic has few political friends.

Looking at how the MEPs are voting is a useful indicator of how they will vote on future ordinary legislation. For some, like GMOs, there is broad and significant cross Party opposition in the EP.

The Commission's follow-up responses to successful challenges are useful. They have ignored all implementing act challenges. For RPS measures and delegated acts, they can't continue.

If timing is a challenge for the EP to undertake the proper scrutiny, the Commission will withdraw the proposal, rather than offending the EP.

It is a considerable amount of work to prepare a successful challenge. I estimate around a week's work. It is not a small undertaking and not done lightly.

The time you know a challenge has started and the vote is short. If passed, you usually have two weeks before it goes to the plenary.

Most secondary legislation gets adopted without any detailed oversight.

Can a lobbyist block secondary legislation?

2nd April 2018
Comitology

One of the greatest professional challenges any lobbyist will face is to stop a piece of secondary legislation being adopted.

If the European Commission has tabled a piece of secondary legislation you oppose your chances of getting the European Parliament or Council to block it are slim.

Your chances are slim. The best thing you can ever do is invest your time and resources up front and get the Commission to table the proposal you want. If they don't, you are going to be playing catch up.

NGOs stand a better chance of getting the European Parliament to take up the challenge. They focus on a few sensitive issues, such as GMOs, chemicals, pesticides or children's health.

Every time I have faced this challenge I have resorted to my trusty comitology bible from PACT, process charts and guidebooks.

Case Studies

I have written some more detailed post on specific challenges:

Glyphosate

Endocrine Disruptor Criteria

Environment Committee's challenges

Triton

Having dealt with many of these cases, you'll find Member States reluctant to take up the issue. Officials will tell you that even if they could persuade the Minister to take up the issue, they are not going to supplant their judgment over that of any independent scientific expert.

I am not saying it is a theoretical possibility, but I am saying that your chances are at best remote.

It is important to remind your client how difficult this will be. This is not a time for false hopes.

Veto or disapproval

If the measure you are contesting is an implementing measure, MEPs and the Council can voice disapproval. They can't block it.

If the measure is a delegated act or RPS, the European Parliament can block it.

Voting

The system makes it very hard for the Commission's proposal to be blocked.

For the European Parliament, you need 376 votes or more to stop it. Getting an absolute majority of members to vote in support of one issue is never easy.

For the Council, you'll need a Qualified Majority against the Commission's proposal. Not impossible, but it is rare.

So, the basic learning is to make sure the Commission put's the right proposal out the door.

To be fair, you really need to be focused on the design of the original legislation. If it says you can't get an exemption for the reason you want an exemption, your cause is lost before you have even begun. It's just too late.

Jump over hurdles

You are going to have to jump over some very high procedural hurdles.

In the European Parliament, you are going to have to:

1. Find someone to support you
2. Get it past the lead Committee, and if passed
3. Get 376 votes in support of the challenge – see this piece on Canadian Oil Sands challenge

What arguments work

In my 20 odd years, I have noticed some trends on why secondary legislation gets blocked.

- A substantive error of law
- Procedural errors
- Ignored something obvious that should have been taken into account

Most of the successful challenges are around public health issues.

Politics does not work

I am sure that one day, the European Parliament or Council will intervene for other reasons.

I don't think that there will be enough Member States or MEPs who will start second guessing regulatory scientists.

There are many MEPs and Member States who will intervene for NGOs or industry to support their cause.

That is is not in doubt. Politics will always step in.

What is more important is whether there will be an absolute majority of MEPs and a Qualified Majority of Member States for you – that threshold is very high.

The high number of the hurdle of political reality you can't ignore.

If all else fails – goes to Court

If you can't get enough votes to block, you can always see if the Court (see Denmark v Commission) will step in..

Environment Committee votes against REACH Restriction on lead and PVC

14th January 2020
Comitology

The full Parliament will vote on Environment Committee backed challenge on Wednesday 12 February.

This will be a precedent-setting challenge to a proposed REACH Restriction.

If the EP blocks the proposed Restriction, both the Commission and ECHA are going face some difficult choices.

Update (21/1/20)

This morning (21 January 2020) the Environment Committee backed the challenge.

The vote

42 for, 22 against, and 4 abstentions.

The EPP and ECR voted against.

The vote in the full Parliament will be in February.

Link

EP Environment Committee Press Release (link)

On Tuesday 21 January, the Environment Committee will consider and vote on a test case for the circular economy.

It centres on contamination by legacy substances (lead) from entering the European market via imports. Lead in PVC is already phased out since 2015 by way of a voluntary agreement.
But, lead in PCV continues to come in through imported articles. This is because the voluntary agreement does not cover imports.
The challenge contends that 'recycling should not justify the perpetuation of the use of hazardous legacy substances' (para P).
The outcome of the challenge will set an important precedent.

Objection pursuant to Rule 112(2), (3) and (4)(c): Commission Regulation amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of

Chemicals (REACH) as regards lead and its compounds

The draft motion is backed by: Bas Eickhout (Verts/ALE), Maria Arena (S&D), Martin Hojsik (Renew)

The text is below.

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European Parliament

2019-2024

Committee on the Environment, Public Health and Food Safety

2019/2949(RPS)

13.1.2020

DRAFT MOTION FOR A RESOLUTION

leadPVCchallenge

pursuant to Rule 112(2) and (3) and (4)(c) of the Rules of Procedure

on the draft Commission regulation amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards lead and its compounds
(D063675/03 – 2019/2949(RPS))

Committee on the Environment, Public Health and Food Safety

Members responsible: Bas Eickhout, Maria Arena, Martin Hojsík

Why Commission wants to avoid public scrutiny of the 15th ATP

7th February 2020
Comitology

The feedback from the public consultation can be useful. It can raise points officials don't like to hear and show that an issue is more sensitive than they ever thought.

Sunlight in lawmaking is healthy but some people think it gives a bad skin rash.

Due to the switch over of CLP ATP updates to delegated acts, the Commission ran a public consultation for the 14th ATP. You can find it here.

At the time, the Commission Services were instructed to do this by the Secretariat-General. They say it was a clerical error.

You can understand why. Afterwards, a lot of Member States used the evidence brought up in the public consultation as the basis to vote against the proposal.

I guess that bad experience is the reason why they have dropped the feedback period for the 15th ATP.

Environment Committee discuss objection to TiO2 classification – Updated

2nd December 2019
Comitology

Today, 3 December, the Environment Committee voted against the objection.

The vote was: Against: 46; For: 19;4 abstentions

The ECR have the option to re-table the objection to the full Parliament (plenary) at the 16-19 December 2019. The threshold for adoption in the plenary is high: 376 MEPs out of a total of 751.

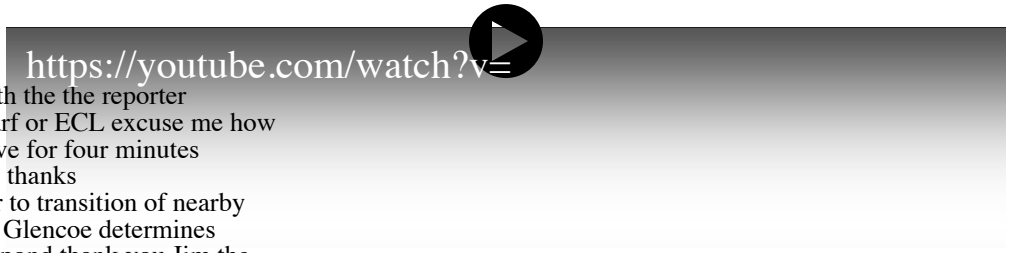
Today, 2 December, the Environment Committee of the European Parliament discussed the objection to the classification of TiO2.

If you missed it, you can watch the exchange of views, or read the automatic transcription below.

The vote is tomorrow morning, Tuesday 3 December 2019.

If the Committee backs the challenge, the full Parliament will vote on it on between 16-19 December. To succeed. it needs at least 376 MEPs supporting the objection.

If the Parliament objects, then the measure won't enter into force.



so let's start with the the reporter
another live scarf or ECL excuse me how
much time I have for four minutes
maximum okay thanks
yep an observer to transition of nearby
so discuss your Glencoe determines
Rashida she respond thank you Jim the
debate on titanium dioxide is already
underway colleagues I must say that I
wasn't persuaded by mr. Hansen's
argument says it's not a question of
belief it's a question of solid evidence
I am opposed having looked at all the
documents and with a view to the
environment and protecting our citizens
I find that this debate has been
dragging on to two years now and yet
there's still no fresh evidence the
Commission doesn't have any either
a very expensive study was commissioned
on rats and it was felt that the results
could be extrapolated just as they were
to humans well of course the important
thing here is classification we're
talking about taking ti2 upper category
saying it's a carcinogen but within the
context of health and safety at work the
reason for that is that most of the time
the substance appears in powdered form
well first of all we need to tackle this
substance in the directive dealing with

working conditions then what we're dealing with here is a situation where people would not actually be exposed to titanium dioxide in the same way as they are now
furthermore it's unacceptable in the absence of any first studies that we should change the classification in this way the reason I say that is that titanium dioxide is used in thousands of products thousands of products and there are no studies there's no evidence which would bear out the hypothesis that there are presumed threats to human health here titanium dioxide also has specific properties particularly when it's in contact with nitrogen dioxide we've no new evidence no new analyses so on top of that there's no financial analysis that would give us a clear idea of the cost of replacing this substance so against that for context I think I have every reason to oppose this proposal we need to analyze working conditions first of all perhaps the working conditions directive needs to be amended on these lands discussion structured with the political groups so starting with the EPP who takes the flow for the bb-better thank you for giving me the flow well I would like to explain that in please simply we are not against the classification of the tanum dioxide but we are cpp find that the classification as potential or suspected carcinogen creates a lot of uncertainty and might have negative consequences in various industries in the recycling process of the Saturn materials and the downstream occupational health and safety standard I note that the classification we'll only apply to waste in powder form containing one percent or more of the tannin dioxide
however powder is not divided and therefore it creates room for various interpretations that might affect projects even financed by the use such as the processing of bauxite residue I also think that for such a critical decision to be made more scientific evidence should be required I understand that it's harm to health has been provided by tests on rats and I also recognize the time that it is required for such studies to be conducted and lead to safe conclusion that's why I would like to vote in favor of the objections since the Commission is ready to provide some further explanation and of course additional additional information on the only proposal that the Commission has already table thank you very much queue for a sandy represent us here it's not here I don't know the topic but I can tell you that [illegible] but I will not be able to argue why but

this is our position I do apologize
it is science-based for Remy I think
which are here we must distinguish the
ring Europe is not fully united on that
majority of the group is against the
objection with with arguments that the
cancer is big risk and want to protect
them workers however myself
I'm arisen coming from industrial
affairs so I know what people do how to
protect them and I don't agree with the
arguments of the chair of eka
the workers fellow training so even no
matter labeling if they don't have good
training they will not be able
follow it here I see that there is no
reason to question whether the compound
is toxic or not but whether there is a
way how to find the sustainable way and
sustainable way is going via this
occupational limit because this can
address both concerns on the health risk
and as well of the professional agencies
working with that with that chemical and
to accent the risk is in the powder form
in high concentration and Lok long
exposure this really means with when
operating with the powder not all with
the final product which is produced and
then being distributed over the citizens
so myself personally I am in favor of
this objection thank you thank you for
the Greens Sperrys yes thank you very
much I must admit I'm a bit surprised
because I've recognized the EPP on that
you are very keen on fighting cancer and
so I find it a bit difficult to believe
that now we should be up you should
object to a label for cancer organic
substances I think this is a little bit
contradictory and it is not as what some
some have pointed out that we need more
scientific proof of that I mean we do
have as mr. mr. Hanson has said we do
have the aircar assessment we do have
the assessment of the iIRC which goes in
the same direction so we have a clear
assessment this is a cancer organic
substance and all we want is a label do
not breathe dust a sprain I think we
should give workers but also consumers
this level of information in order to
prevent them from harm thank you very
much
thank you for I have no speaker
for each chance no it's it's for for ID
okay please go ahead we miss seemed
thank you very much chairman well our
position is the one that we've supported
for a long time as you well aware on
because carcinogens I'm not sure that
it's through applying an objection that
we can come back to the basic standards
when it comes to labeling and how should
I put it a revaluation of products
everything should be going in the same
direction protect workers as
greater to a great extent as possible

including through the companies so we
have to protect workers it's not sure
that through this objection we can make
sure that we can protect workers
sufficiently yeah thank you Jim
although we've taken the first step to
classify a titanium oxide flea and born
consumers fluid something says such as
the painter being left out of the
picture if it's been struck between
protect public health and business life
that's the essential problem with this
regulation there's a need to protect our
health and you therefore can't make
compromises the financial demands the
the highest classification should apply
to these carcinogens you need a thorough
serious replacement strategy the
Commission hasn't had any Democratic
support from Parliament and the member
states appalled authorizing GMOs that
they push them to on the basis of in
Thomas now
they are required to follow the risk
assessments committee in this instance I
read understand that how our colleague
can raise the objection
and and just brush aside consumers and
workers right to have the health
protection I cannot support this
objection which you know perfectly well
has been written by the lobby yeah Thank
You chair and I will speak in German
yeah how cool Egon death is clad as we
yes obviously in the EPP we are
confronted with this every time that we
want to fight cancer so like the greens
but we're very precise when it comes to
looking at things and recently I spoke
to the German Cancer Research Center and
in there's a lot of research on the
causes of cancer when it comes to the
chemicals we're looking at it couldn't
10th point any deaths in the EU we must
take it very seriously and our colleague
asked specific questions we said we'd
reject it we happy to look at the
specific points the fact is in Germany
though the organization dealing with the
protection of employees says the
exception is unnecessary or have
necessary rules to protect employees and
the labour minister who is from the
Socialist Party says the same thing we
must see whether this helps really I
have three specific questions the
Commission first of all is it correct
what the mover of the omission says that
there's
the only evidence is with animals and is
there any evidence as regards humans can
we said that send us to us in writing by
tomorrow morning in the the Commission
note says the effects of recycling will
be minimum but what are the effects that
can be observed thirdly how exactly what
labeled there is a risk if there's no

labeling if it says because if you scrape off the paint it might cause cancer what exactly is being proposed 'old and employees need to know what they should do so that there are exposed to this dust and certain more things which might be more problematic so what will exact what type of labeling exactly will they be so I will give the floor to the Commission the govt to end this session thank you very much thank you for the opportunity to come here to discuss our decision to classify it Italian dioxide as a carcinogen category 2 so as you very well know the objective of the of the CLP regulation is to protect to achieve a high level of protection of your health and environment and this is done through the identification of the hazards so the intrinsic properties of the substances there are two ways of classifying either allow an industry to do surf classification or through harmonized classification which is initiated either by member state or by by industry itself the classification labeling and packaging regulation indicates that for carcinogen processes are carcinogens and particles or category to harmonize classification is the right way the right way forward so the proposal that the decision that we took was based on the on the opinion of the risk assessment committee in akka as you know is the science-based committee that looks into proposals by member states or by industry and since the the risk assessment committee emitted its its opinion as some of you have rightly say there has not been any single piece of new evidence that will put into question the decision of the risk assessment committee so the only science base opinion that we have is that of rock so our classification as I said is based on rock but it's also in line with the conclusions that were achieved by the International Agency for research on cancer which is a w-h-o agency that identified that engine dioxide as a possible carcinogen to humans and it's also in line with other measures taken by the Commission and in the European Union such as to ban the use of titanium dioxide in nano form in cosmetics that can be strained also because they can be hailed so so we believe that our decision is a solid science-based let me just comment on the issue of whether the classification level in a packaging is a better option compared to that of worker protection legislation these two pieces of legislation are compatible they are not incompatible they are compatible and complementary in fact the substance is how it has a harmonized

classification under CLP allows well obliges industry to provide a safety data sheet when they are supplying the substance which allows workers to properly handle this after the substance in a safety in a safe way so it's the obligation of providing a safety data sheet that will trigger positive effects in worker protection
additionally harmonized classification assists the setting of exposure limit values and there under occupational health and safety legislation but it's very important to note that the issues of titanium dioxide and the concerns that the use of titanium dioxide races is not limited to work the protection is also an issue for the self-employed that are not covered by worker protection legislation and an issue for consumers that may also be exposed to this substance in terms of the of the consequences that our harmonized classification will have it will improve the information on the hazardous Ness of the substance and help inform choices in terms of safer handling
it will also allow other legislation to take risk management measures to ensure the safety of the of the substance it's important to note that harmonized classification only has to rely on this on the intrusive properties of the substance on the hassles of the substance and not make considerations of the risk that is of exposure some of you have have made one of the Honorable and this has made a reference to to the fact that powder is a salamu Sturm and therefore will have problems of enforcement I would like to remind that rock recommended that the substance should be classified as casino chain category two violation in the Commission decision the substance is classified in powder form for particles with an aerodynamic diameter of equal or less of 10 micro millimeters so we are given a specific diameter for this for these particles which we consider response to those particles that can be inhaled so it's a very specific diameter and hence for this allows enforcement of the decision there was a question whether we only have Studies on animals indeed we had a Studies on animals that I was mentioned before have been provided by by industry and it's the fact of the relationship between the results on the study of animals and the potential to extrapolate this to to humans that it was decided that the rock decided not to classify the substance as carcinogen to Castleton 1b but rather carcinogen 2 so the relationship between the studies and animals and the and and the concerns for humans was currently taken into account in the decision of the of the risk

assessment committee what has been
labeled was also asked so the substance
will have to be labeled as well as the
as the mixtures that are classified
those are the misters in the powder form
there are some issues that will not have
to be classified according to our to our
decision and those
the liquid mixtures but they will have
to be labeled so although they are not
classified they will need to be labeled
and explained that they contain there
may contain respirable particles and
that would be a warning attached to this
to this label and the warning will read
hazardous respectable – maybe for when
use or droplets may be formed when used
do not breathe it so that is what will
have to be labeled and I think that's
replying all the questions that you have
just to conclude that for the new
commission that just took office today
the fight against cancer is an important
priority and there is only one way to
fight cancer is to identify the
substances that cause cancer and without
the
English

Section 3

16th February 2023
Uncategorised

ST DOCUMENT — TEST DOCUMENT — TEST DOCUMENT — Document doesn't look right? We'll help you out! — TEST DOCUMENT — TEST DOCUMENT — TEST DOC

What to do if you have only 4 weeks to turn things around?

1st October 2018
EU

Around 97% of the laws the EU adopts each year are secondary legislation. Unlike ordinary legislation, most of the time the College of Commissioners are blind to what's being put out the door in their name.

Rarely, when dealing with politically sensitive files, like the Fuel Quality Directive and the Endocrine Disruptor Criteria, the College of Commissioners step in and decide.These are two exceptions. I worked on both of them.

Technocrats make the law

Most people in Brussels prefer technocrats to make the decisions for secondary legislation. This makes a lot of sense most of the time. I doubt Commissioners want to scrutinize where air quality monitoring machines are meant to be placed.

99% of the time this is not going to be a problem. I think that 1% of the time something is going to get through that really deserves the political scrutiny of the Commissioners. These are stories that the anti-European press feed on.

The chance that the Commission can weed out suspect proposals is low. Most secondary legislation does not benefit the review provided by Better Regulation. Today, only a small percentage of initiatives get a road map and even fewer benefit from an impact assessment. The Regularity Scrutiny Board can't step in a point out that the earnest technocrat got the case wrong, developed amnesia for subsidiarity, or forget the limits created by the enabling legislation. The only people who benefit are the anti-European media.

I've worked inside the Commission and Parliament passing laws. The truth is most officials and Parliamentarians are hard working, dedicated and informed. Yet, none of them, even the most talented, had solved the problem of knowledge.

Checks in the System

Good governance puts checks in the system. Some technocrats don't like it – their freedom is restrained – but the best support it.

The real checks for secondary legislation come down to this. First, the proposal needs to go through interservice consultation. Second, after that interservice consultation, the draft delegated and implementing acts are made public for a 4-week public feedback. Third, after that the Commission adopt the proposal.

Member States and MEPs get to scrutinize proposal. Getting them actively involved is hard to do. I write this as someone whose pulled this off more than once.

I readily admit that the chances of changing things substantively once the Commission put something out the door are limited.The longer a file goes on, there is less chance to genuinely influence things positively.

Indeed, for implementing acts, if the College of Commissioners wake up very late in the system and realise things have gone very wrong there is nothing they can do about it. The rules provide that "Where there is a qualified majority in favour of the draft implementing act (positive opinion), the Commission is required to adopt it (Article 5(2) of the Comitology Regulation)." The Commission hands are tied. They can't act even if they wanted to.

[1] Inter-service consultation

During interservice consultation, the Cabinet can press a button to accept or block a proposal.

In practice, the system stands and falls on herd mean service and cabinet officials. After all, they have to make a judgement based on a short description about the proposal.

For example, when they are looking at proposals about chemicals, they get to look at text with the full scientific name, a name that is so rarely used in practice, no-one other than the desk officer knows what the proposal is about.

The services and overworked cabinets have 10 to 15 days to understand the ramifications of the proposal and annexes. It is going to take a remarkable political official to pinpoint that a new proposal on page 22 of Annex II, point 5, has been inserted from out of the blue. The Cabinet official won't know if it has been inserted at the request of a member state, interested group, or act of revelation.

Officials have no incentives to highlight the sensitive elements in a proposal. That's going to send the proposal up to the College and increase their work load a hundred-fold.

Anyway, interservice consultation is not public.

See my blog post here.

2. You have 4 weeks to turn things around

You really only have one slim chance to make a difference. Secondary legislation now has a 4-week public consultation. Directorate-Generals look at the feedback. You can than raise the evidence and sweet merry hell. The Commission has – like for mobile roaming charges – stepped in and withdrawn poor proposals.

You can track it here.

Not enough people take this opportunity. Take it. But, realise you are dealing with civil servants, so highlight the procedural breachs, how the text ignores the spirit and letter of the law, or is based on fake evidence.

Don't go for green ink 62 page submissions citing strange conspiracies – the don't work.

Recommendations

There is no practical way the College of Commissioners can filter all the proposals going out in their name. A regulatory state needs some political control to make sure that the 1% of the 97% of proposals are not barmy and open up the EU to ridicule.

So, until officials solve the problem of knowledge combined with superhuman endurance, these simple fixes would improve things:

1. The public got to know when the proposal was entering Inter-Service Consultation
2. Allow for five-day public consultation on all inter-service consultations. Most of the time, there will be nothing to say, but once in a long while, someone is going to point out the Commission's about to propose something silly
3. A unit of officials reporting direct to the President with the mandate to scrutinize each and every proposal. They should be able to block any proposal that does not add up.

Source: Guidelines for the services of the Commission Implementing Acts and Delegated Acts

The Many Chances to Let the Commission Know Your Views

25th July 2018
EU

You have the chance to let the Commission what you know about virtually every step of the way. Just go and visit 'Have Your Say'. The only chance the Commission come forward with anything that surprises you is if you have been living off grid with no contact with the internet or you have been sectioned.

Chances to feed in

They are calling out for your input:

Feedback on	Time for feedback	Link
Road Maps & Inception Impact Assessment Initiatives – when the idea is being developed	4 weeks	here
Public Consultations – when the policy options are firmed up	12 weeks	here
Feedback on legislative proposals – when the proposal has gone out the door	8 weeks	here
Draft secondary legislation – what do you think of the technical measure	4 weeks	here
Rules that need to be changed – lighten the load – what do you think should be changed		here

Making it easy for you

If you do not want to click on a web link, you can subscribe to updates, and have them sent to your email box. Here is the link.

Through the Road Maps and Inception Impact Assessments, you get a very clear idea of 'ideas' being considered. Then is your chance to step in and frame the policy future.

If an 'idea' makes the way off the drawing board, and is validated by the first Vice-President, or Commissioner for secondary legislation, firmer ideas will be put out for public consultation.

The Commission gives you the chance to provide feedback on ordinary legislative proposals that put out the door. They even send it to the European Parliament and Member States in the Council. Now, I am not sure whether MEPs or government attaches negotiating the text read the feedback. But, it makes sense, if you think the issue is important enough, to put your well-reasoned feedback on the record.

The most useful section is tracking upcoming secondary legislation. As that is around 97% of EU laws, it is important to follow, and most people ignore it.

They are even giving your time time to feedback. They are no 'answers by the end of the day'.

Are there gaps?

Yes there are gaps. The system is not perfect. It has improved a huge amount, but it can improve.

The main missing gaps are knowing when (1) 'validation' is given and (2) when the all-important 'inter-service consultation' starts. Knowing when these two events occur would be useful. To be fair, it would help Commission officials making it public will help a lot of officials, who don't have the time to track the initiatives being cooked up in their own department, let alone in other departments.

Sometimes, urgent and important proposals skip the process. When the migration crisis hit, measures

I guess the only challenge is for the blind, the illiterate and let's not forget those living deep off the grid and the sectioned.

Do they listen?

The simple fact is that daft ideas and proposals that have snuck through have been pulled.

For example, someone in the Commission tabled technical roaming charge rules that seemed designed to favour telecom firms. The public let the Commission know. The political grown ups in the Commission stepped in and pulled the proposal.

The system works. If you want to change something, you need to make a strong case. Wailing to the wall is not going to cut it.

Real facts not pub facts needed

It is an 'evidence based' approach . That means you need to provide evidence. That means data to support your point.

This means facts. Not pub facts, but real facts. Too many people use pub facts. Don't. You are wasting your time. Pub facts may persuade inebriated acquaintances down the pub, and may well pass as news in the Daily Mail, but they don't count.

It does not mean wailing at the walls. By evidence, I mean sober, analytical , reasoned supporting analysis that supports a particular policy choice or outcome. If you want to see a good example read 'Factfullness' by the late Hans Rosling, or anything by Vaclav Smil.

Policy Wonk Fantasy

To be fair, officials are left to sift through a lot of dross. Most submissions miss the point and ignore putting forward any evidence.

It's a policy wonks fantasy. Think tanks and umber crunchers of the world must be in ecstasy.

In reality, too few people have 'real facts' to support their 'world view'. Open law making calls them out. They'll need to stay with pub facts.

A primer – Inter-Service Group to Inter-service Consultation

19th September 2019
Case Studies

Inter-Service Group to Inter-service Consultation

1. **Inter-Service Group**

An impact assessment is required for Commission initiatives that are likely to have significant economic, environmental or social impacts.
Work for major initiatives can begin once political validation by the First Vice President, Vice President, Commissioner and in close collaboration with the President.
The political validation requirements are below:

Table 1. Political validation of initiatives and linked requirements

Initiative type		Who validates?	Roadmap or inception IA?	ISG needed?
"Major" initiatives (*Decide entry at least 12 months prior to adoption*)	All major initiatives	FVP & VPs & Commissioner in close collaboration with the President	Yes	Yes
"Other" non-major initiatives (*Decide entry*)	Initiatives which are neither "major" nor evaluations or fitness checks (*Decide entry at least 3 months before adoption*)	Commissioner	No	No
	Evaluations & fitness checks (*Decide entry at least 12 months before completion*)	DG (*Management plan*)	Yes	Yes
Initiatives handled outside Decide		DG	No	No

The IA is led by the lead DG. The IA is prepared by an interservice group (ISG) which will steer the IA process and collectively prepare the IA report.

Under an earlier version of Better Regulation, the ISG was known as the Impact Assessment Steering Group (IASG) (link).

The Secretariat-General will lead ISG when the item is in (1) the Commission's Work Programme, or (2) an important initiative, or (3) a sensitive initiative. Otherwise, the lead DG steers with the help of their DGs Impact Assessment unit.

Along with the lead DG, all other relevant DGs will be involved. The relevant policy unit within the Secretariat-General and Legal Service will be present. Additional expertise from other DGs needs to be drawn in, such as as economic analysis (e.g. ECFIN), scientific research and analytical models (e.g. JRC), social impacts (e.g. EMPL), SMEs, competitiveness (e.g. GROW), environment (e.g. ENV), fundamental rights (JUST), innovation (RTD), digital/ICT (CNECT) etc.
Some ISG can be large containing over 40 officials. The bottom of the ISG is that it provides you with a lot of opportunities to provide additional input. This is dependent on you having already provided e substantive submission during the public

consultation.

If you choose not to participate in the inception impact assessment or provide little to no supporting evidence to support your case, the chances of you being listened to during the adoption phase are limited.

The quandary is that the impact assessment model is rightly evidence heavy. Data, studies and information are the currency of influence. Many find 'evidence-based policymaking' hard to accept beyond slogans.

Too often, weak evidence, conjecture and passing off correlation as causation are exposed. Your weak case is rejected.

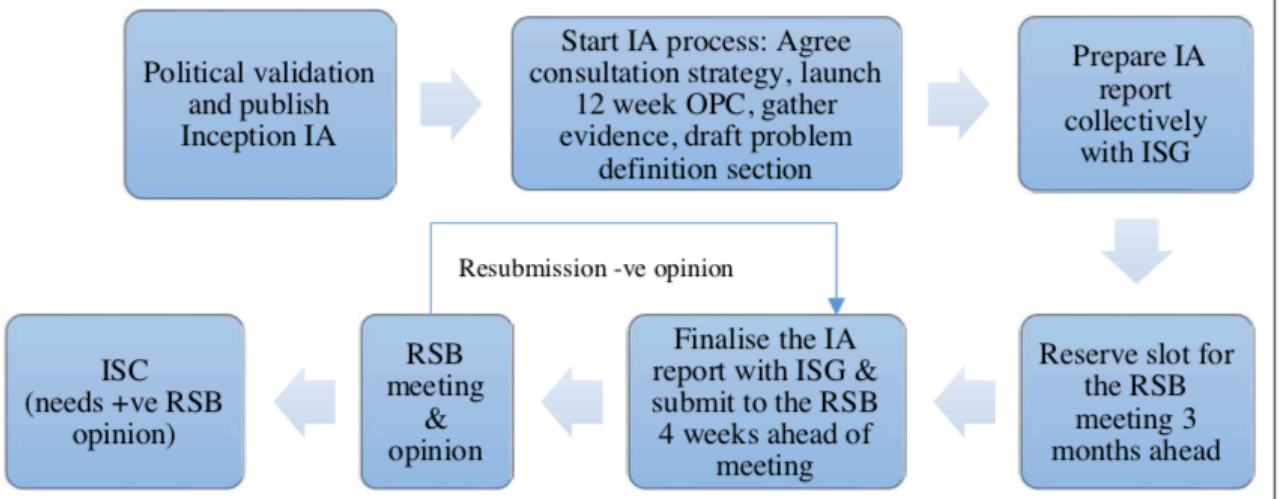
Instead of accepting the weak case, many instead choose to attack the impact assessment in self-pitying anguish. It serves no better case than self-prescribed therapy. It changes nothing

Sometimes, the lead DG is unacquainted with the rigour required in preparing an IA. As the exercise is set up to avoid confirmation bias, or writing up the conclusions at the start before any evidence is presented, the file is sometimes handed over the SG to complete.

Preparing a good quality Impact Assessment is not a slight ordeal. Yet, a good quality impact assessment helps strengthen the policy and later on, the political case, for the final proposal.

The process lasts around 12 months and follows these steps.

Box 1. Process to prepare a typical impact assessment



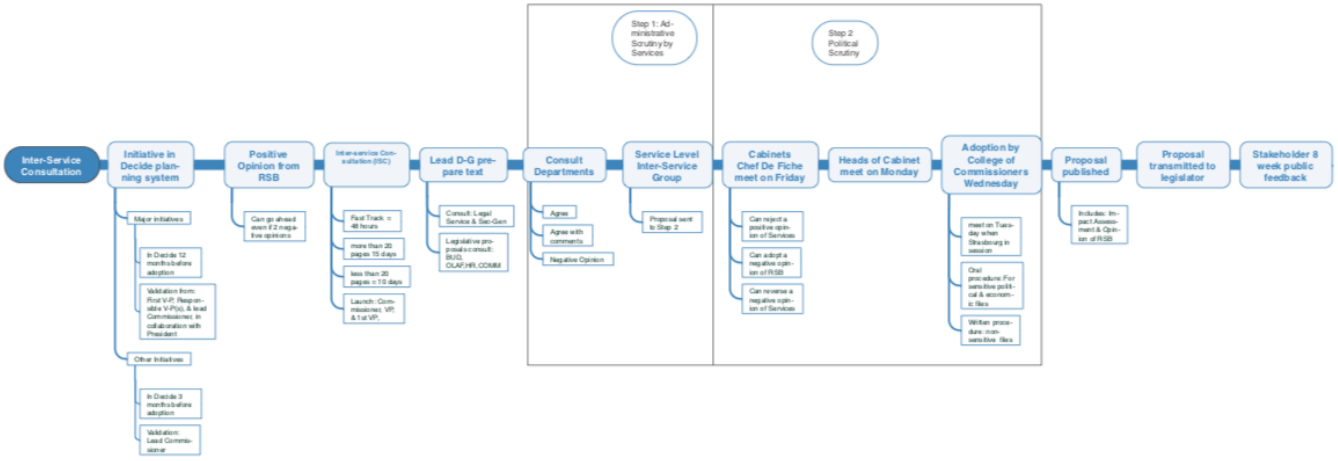
The time needed will depend on the evidence which is already available, the need to rely on the results of study contracts etc. Typically up to 12 months although can be significant shorter.

You can summarise the process like this:

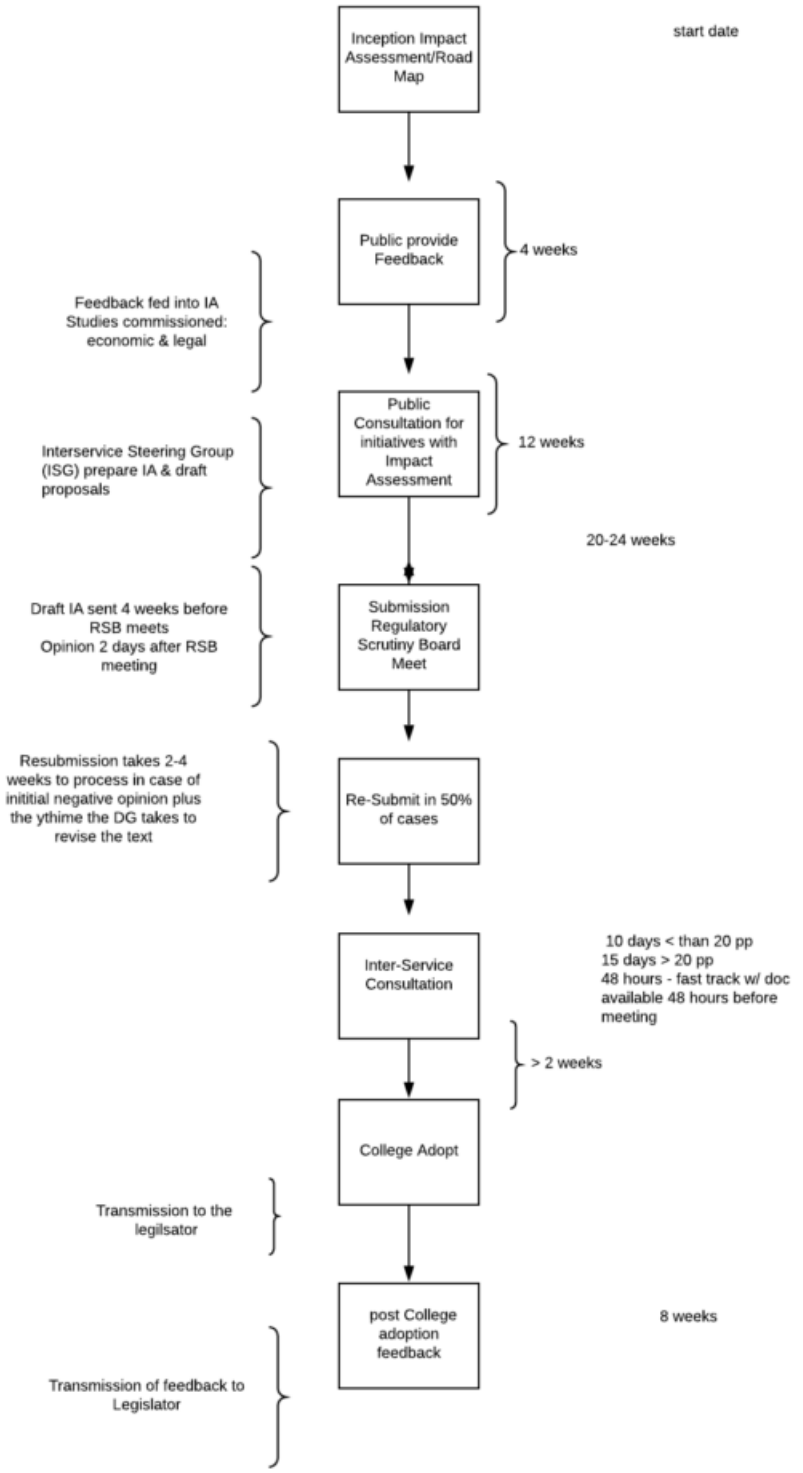
Inter-service Consultation – Political Adoption

After the Impact Assessment is approved by the RSB, it can move from preparation to adoption.

See chart below:



Fortunately, the Commission spells out the mechanics of adopting proposals clearly. There is a helpful note from the



Commission on their 'Working Methods'. the_working_methods_of_the_european_commission_2014-2019_november2014_en

The adoption procedure is in two distinct steps. First, there is consideration by the Services. The Services are consulted on the draft legal text, the impact assessment together with the opinions of the Regulatory Scrutiny Board.

The second step is the political scrutiny by the Commissioners. Here the College of Commissioners can adopt by the written or the oral procedure.

Adoption by written procedure requires all Members of the College to give their positive opinion. Any objection must be lifted via bilateral negotiation for adoption by the written procedure to proceed.

Step 1

- Departments with a legitimate interest in the proposal

The following department usually has to be consulted:

- Legal Service
- Sec-Gen
- Human Resources
- Budgets
- OLAF
- Communications

If the lead Department does not follow the correct procedures, the Sec-Gen can intervene and suspend the procedure until the errors are rectified.
The Departments can say:

- No Opinion/ No Answer
- Positive Opinion
- Positive Opinion with comments
- Negative Opinion

The lead department then works to incorporate the changes.
Who is involved
Not too many people involved. Those engaged in the proposal come from:

- Inter-service Group
- Director Generals
- Chef de fiche – Cabinet Officials working on the file
- Heads of Cabinet
- Commissioners

In practice, you are dealing with around 20 people.
Finding out who follows the file in the Cabinet is easy enough. Their official portfolio is posted on-line. However, double-check that they are still there – there is a high turnover.
On sensitive files, there is a fast track process of 48 hours, where document circulation is limited to a few officials. For particularly sensitive proposals, there is a confidential reading room where officials visit to review the files.

Step 2

When an agreement is reached at the Service level the file is given over to political validation. Most of the time the Commissioners agree with the proposal and there is no disagreement. Rarely there is a vote in the College, but it is very rare. For example, on 6 November 2013 then Commissioner Barnier voted against placing on the market for the cultivation of a maize product Zea mays L.
If they can't reach an agreement, the Commissioners will go several rounds looking to reach an agreement. After a few rounds, the President's Cabinet will step in to reach an agreement. Back in August 2009, on Blue Fin Tuna CITES listing, the internal wrangling went on over the summer. The Director-General of DG Environment got annoyed that his Commissioner was ignoring his advice. His Commissioner won the day.
You can find the agenda and minutes of the College meeting at
https://ec.europa.eu/transparency/regdoc/index.cfm?fuseaction=gridyear
The minutes are at best opaque. The best sources on what really happens in the College is Politico, the FT, and Liberation's Jean Quartremer.

Why lobbyists need to use maps

7th April 2019
Political Communication

The Map is not the Territory

Parrish writes " All are models or maps that simplify some complex territory in order to guide you through it. Just because maps and models are flawed is not an excuse to ignore them. Maps are useful to the extent they are explanatory and predictive" (Great Mental Models, page 40).

When you work to influence public policy or lawmaking, you are treading along a well-worn path. Whether you use them or not, there are detailed maps, that will make your journey more successful.

Basic Maps

The basic maps are:

- Better Regulation Guidelines and Toolbox
- Guidelines for the Services of the Commission on Delegated acts and Implementing acts
- EP Rules of Procedure
- Council Rules of Procedure

The map is not reality

Often, it is useful to use a map of the map. I find process charts and checklists make the journey easier.

The map is not the territory. The model is not reality. The London Underground Map is useful for passengers. It's not the same map used by the drivers.

You need to check the map against reality. Events can intervene. Sometimes you'll be work to find a way to by-pass established pathways, and then you may work make sure the usual process is followed.

How Many Maps

As I spend most of my time working on the decisions of Agencies, I personally use a series of well-worn maps. Operationally, this is around 50 maps, which I have chunked down into process charts and case studies.

I update the maps in light of developments. The decisions and votes in the Council, EP, Commission, and regulatory agencies, mean the maps need to be re-looked at regularly, and updated in light of events..

Using the maps takes out the guesswork from the journey. They are not perfect representations of your journey, but using them makes your journey a lot easier. Especially if you have never taken that journey before.

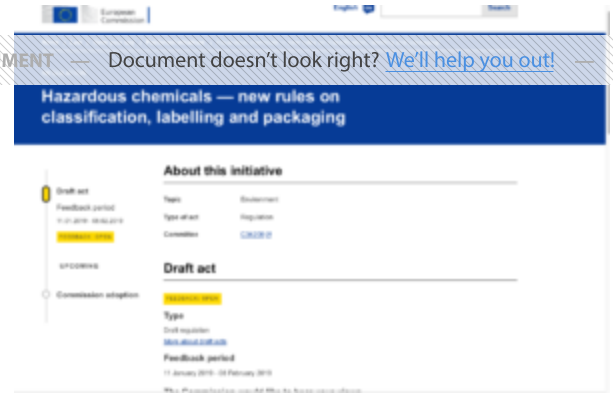
Chunking down every step in the journey of a law

Step

1. European Council's Road Map European – **Council**
2. Commission's Political Priorities – **Commission**
3. Setting the Commission's Work Programme – **Commission**

4. Mid-August preparation – **Commission**
5. College retreat end August – **Commission**
6. State of the Union 9 September – **Commission**
7. Work Programme late October – **Commission**
8. Joint Declaration – **COM/EP/Council**
9. Can new ideas come into W-P – **Commission**
10. Political Validation timetable – **Commission**
11. Political Valaditiation of Major Initiatives – **Commission**
12. Political Validation of non-major initiatives – **Commission**
13. Tracking new initiatives – **Commission**
14. Road Maps – what & when – **Commission**
15. Inception IA – what when – **Commission**
16. Interservice Group – **Commission**
17. Stakeholder Public Consultation – **Commission**
18. Review of Stakeholder Consultation – **Commission**
19. Draft Impact Assessment – **Commission**
20. Key questions of the Impact Assessment **– Commission**
21. Role of RSB – **Commission**
22. Why you can't lobby the RSB – **Commission**
23. Revision of IA – **Commission**
24. Draft proposal – **Commission**
25. Validation to launch Inter-Service Consultation – **Commission**
26. Who decides on ISC – Services – **Commission**
27. Who decides on ISC – Political – **Commission**
28. How long is ISC – **Commission**
29. What if no agreement at ISC – **Commission**
30. College adopts – **Commission**
31. How does the College Vote – **Commission**
32. Who sets the College's agenda – **Commission**
33. When does the College meet – **Commission**
34. Commission Proposal – **Commission**
35. Commission Press Release – **Commission**
36. Stakeholder public consultation on a proposal – **Commission**
37. Proposal transmitted to EP – **EP**
38. Proposal transmitted to Council – **Council**
39. Proposal allocated to Committee EP
40. Role of lead and associated committee – **EP**
41. Proposal allocated to Rapporteur – **EP**
42. Role of Rapporteur – EP
43. Can the Rapporteur be ignored – **EP**
44. Shadow Rapporteurs appointed – **EP**
45. Role of Group Secretariat – **EP**
46. Role of Committee Secretariat – **EP**
47. Role of Political Advisers – **EP**
48. Committee Draft Report 1st Reading – **EP**
49. How long can a report be – **EP**
50. How to submit an amendment – **EP**
51. Committee Deadline for Amendments – **EP**
52. Are EP amendments subject to IA? – **EP**
53. What happens if you are late – **EP**
54. Committee Debate 1st Reading – **EP**
55. Recording votes in Committee – **EP**
56. How the Groups prepare their positions – **EP**
57. When do the Groups prepare their voting lists – **EP**
58. Do national groups prepare their own lists – **EP**
59. Role of Group coordinator – **EP**
60. Role of National coordinator – **EP**
61. The link between national party & EP group – **EP**
62. Voting lists from a national government – **EP**
63. The role and power of the Committee Chair – **EP**
64. Committee 1st reading – **EP**
65. Voting rules in Committee **– EP**
66. Plenary Deadline for Amendments 1st reading – **EP**
67. Plenary Debate 1st reading – **EP**
68. Plenary Vote 1st Reading – **EP**
69. Recording votes in Plenary – **EP**

70. Groups voting lists in plenary – **EP**
71. National group voting lists in plenary – EP
72. Trilogue mandate by Committee – EP
73. Trilogue mandate by Plenary – **EP**
74. Commission Opinion on EP 1st Reading – **EP**
75. Role of Commission in supporting EP – **Commission**
76. Commission role in tabling compromise text – **Commission**
77. Commission role in supporting Council – **Commission**
78. The mandate of Commission Services in negotiations – **Commission**
79. Inter-Service Consultation during talks – **Commission**
80. Commission role in tabling compromise text – **Commission**
81. Discussions Working Party – **Council**
82. Working Party develop 'General approach' – **Council**
83. COREPER adopt a 'General approach' – **Council**
84. Council adopt 'Conclusions'/ Political Agreement – **Council**
85. Role of Presidency – **Council**
86. Role of Council Secretariat – **Council**
87. Voting Rules & a Consensus Approach – **Council**
88. Political Agreement – **Council**
89. Common Position – **Council**
90. Commission Opinion on Common Position – **Commission**
91. Common Position Received – **EP**
92. Can the Political Agreement be changed – **All**
93. Committee Debate 2nd Reading – **EP**
94. Committee Draft Recommendation 2nd Reading – **EP**
95. Committee Deadline for Amendments – **EP**
96. Committee Vote 2nd Reading – **EP**
97. Plenary Deadline for Amendments 2nd Reading – **EP**
98. Plenary Debate 2nd Reading – **EP**
99. Plenary Vote 2nd Reading – **EP**
100. What can and can't be tabled at 2nd reading – **EP**
101. Commission Opinion on EP 2nd Reading – **Commission**
102. Conciliation Press Release – **All**
103. Conciliation Joint Text – **All**
104. EP Conciliation Report 3rd Reading – **EP**
105. Plenary Debate 3rd Reading – **EP**
106. Translation
107. Final Legislative Act
108. Can the text be changed?
109. Signing ceremony



Better Regulation comes to Chemicals

15th January 2019
Better Regulation

On Friday 11th January, the European Commission launched a Public Consultation on the update to the Classification, Labelling and Packaging of chemical substances and mixtures (CLP) Annex.

This is the regular update of substances that updates the RAC's opinions. This is the 14th update. This is the first time the 4-week public consultation has been used for CLP Substance Annex updates.

https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-141469_en

The public consultation runs until 8th February.

The feedback can then be considered by the Member State Committee when they vote on 14th February.

This is a welcome development. It provides an opportunity to raise relevant (Better Regulation) issues that may have escaped the attention of those who have considered the matter before.

It is a final check before final decisions are taken. After all, there may be important vital issues – scientific, legal, economic – that officials from the Member States, Commission, Cabinet, and Agency, have overlooked.

It is unlikely that the Member State or Commission officials will encounter anything new. Already, most, if not all views, will have been brought to their attention.

As Cass Sunstein observes, when dealing with the US experience of cost benefit analysis, this review is unlikely to block action. Rather, it tends to land up adding to the case to support action. But, there will be cases, were taking action is not needed.

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EUROPEAN
COMMISSION

Brussels, XXX
[…](2018) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

PART-2018-624757V4

amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2018/669

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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Annexes 1 to 4

ANNEX I

In Annex II to Regulation (EC) No 1272/2008, in Part 2, the following section 2.12 is inserted:

'2.12. **Mixtures containing titanium dioxide**.

The label on the packaging of liquid mixtures containing 1% or more of titanium dioxide particles with a diameter equal to or below 10 µm shall bear the following statement:

EUH211: 'Warning! Dangerous droplets may be formed when sprayed. See information supplied by the manufacturer. Comply with the safety instructions.'

The label on the packaging of solid mixtures containing 1% or more of titanium dioxide shall bear the following statement:

EUH212: 'Warning! Dangerous dust may be formed when used. See information supplied by the manufacturer. Comply with the safety instructions.'

The label on the packaging of liquid and solid mixtures not intended for the general public and not classified as hazardous which are labelled with EUH211 or EUH212, shall bear statement EUH210 in addition.

PART-2018-624758V2

1

Lessons in Lobbying#13: When to step in to influence a Commission proposal

10th February 2022
Good Practice

The adoption of European laws and policy does not happen out of the blue.

After 25 years, I have not worked on a single file, that when looking at the surrounding or recent historical events, led me to be surprised that a proposal was being tabled.

There is a process to influencing Commission ordinary legislative proposals. The window of opportunity to bring your case to the right people, at the right, with the right information is narrow and known in advance.

I am one of a few people who think that process is primary. It's not the issue, or the politics, that are primary. Very few people think your issue is important, or understand it, and they usually deal with it as part of many other issues on their desk. So, understanding how to influence the process is primary.

I like maps that show the steps of where you need to go.

Below is a map of the adoption of one of the hundreds of Green Deals proposals.

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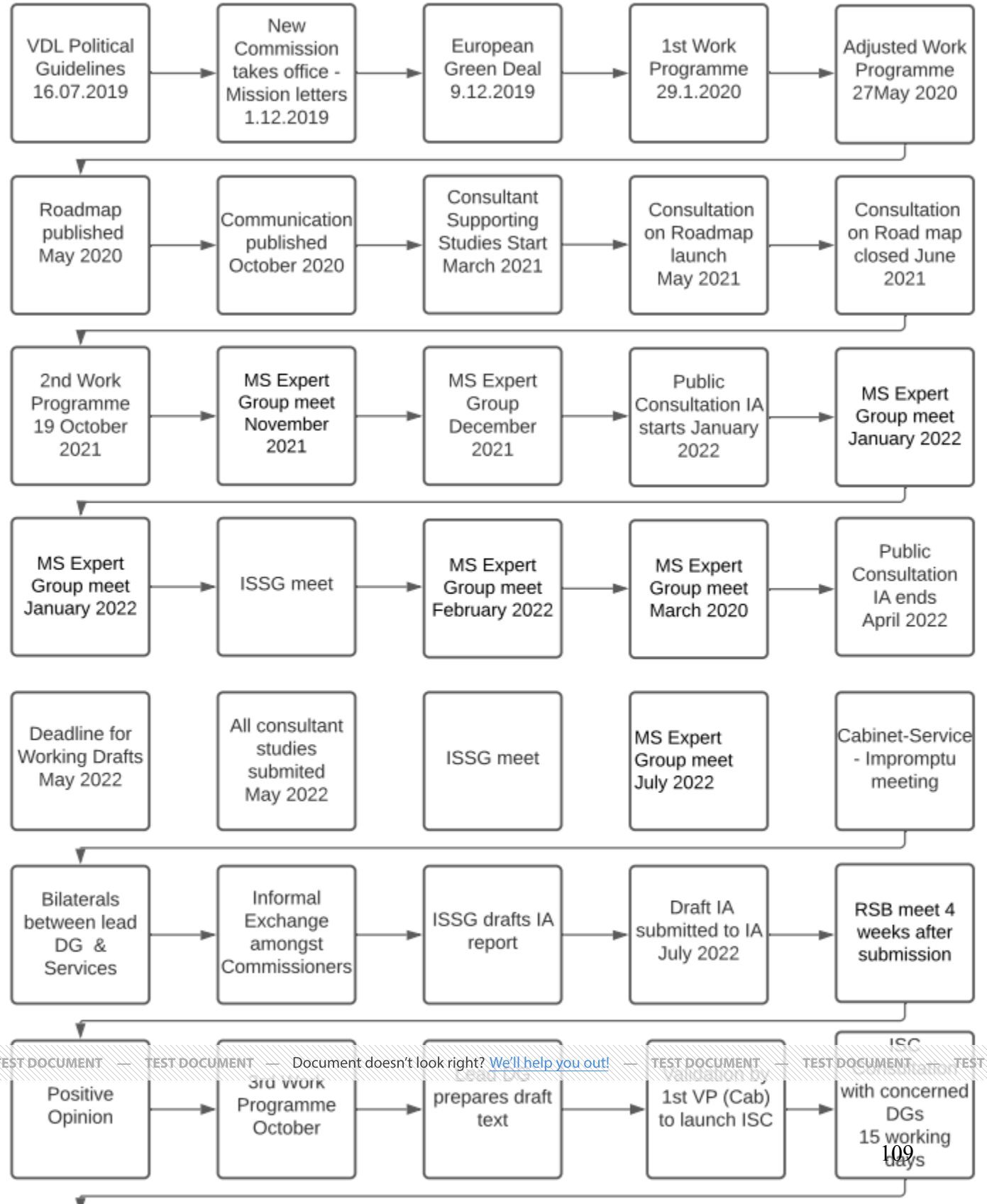


7. You'll need to engage with the officials in the Inter-Service Steering Group (ISSG) and Cabinet issue leads. Again, engage at the right time with the right information.
8. When the file is going into the final stages of adoption, some national capitals will engage with Cabinets. I know of a proposal that got changed in the final weeks after a few Prime minister's offices raised their concerns.
9. Not in the chart is the regular meetings of the lead Council configuration on your issue. Their official and bi-lateral feedback to the Commission influence the Commission's thinking.
10. The formal and informal meetings of European leaders provide an important direction to the EU and to the Commission.

Follow the Sign Posts

On any proposal there are openings to influence the content and direction. They are clearly indicated. If you choose to ignore those opportunities, you'll have little to no influence. And, if you opt for sending a letter to the College on a Tuesday afternoon after the Heads of Cabinet have agreed it, you are wasting your time.

How to be effective in Commission public consultations

5th May 2021
Better Regulation

As the Commission's legislative machine gets into overdrive, there will be more and more public consultations to help mould legislative proposals.

I've made prepared many over my long time in Brussels. It is nice to see your ideas and suggestions being reflected in the final Commission proposal. That's is a nice feeling when you know that idea and solution was off the table. And, over the years, through a process of refinement of making unsuccessful and successful public policy submissions, I think there are some basic things you can do to increase the chances of your ideas and solution being taken up.

If replying to public consultations is new to you, here are some recommendations to make your contribution more persuasive and effective

Recommendations

1. I am surprised at how many people sit out the public consultation process. Whilst silence may be golden in many areas, it is not here. And, if you choose to sit it out, don't be surprised when you are ignored when you wake up late in the day.
2. Don't think that your feedback is going to lead the Commission to change their thinking at the late hour. It's happened, but just don't expect it. Modifying where things are going is a better mindset.
3. Don't go forward thinking that your suggestions are going to be co-opted. You are not being handed the power of the pen to draft the proposal.
4. If your submission shows fuzzy thinking and weak (sometimes no) evidence, the feedback is going to be considered and set aside.
5. It may seem obvious, but if you want to change public policy thinking, you should bring forward a plausible public policy solution that helps remedy the problem raised by the Commission.
6. You need to use evidence. I like robust evidence from respected experts. Pub facts and pub experts won't cut it. Cass Sunstein or Vaclav Smil may not have something on the point you want to raise, but there is rich tapestry of experts out there. Use them. And, your real life experience can make you an expert.
7. Put your best case forward but don't presume your words will be of such revelatory power that officials will back you. Leverage your strong submissions for bi-lateral discussions with the inter-service group.
8. Have the main elements of your submission pre-written. Most organisations are going to find it hard to turn around something clear, credible and persuasive in 4 weeks.
9. None of the questions are surprising. If you read the Better Regulation Handbook (and I realise very few people in or outside the Commission do) you'll get a good flavour of the questions that come up.
10. Highlight any unintended, second and third consequences, both positive and negative.
11. Raise new points. You are not bound to follow the questions. If there is a gap, highlight it. It's why public consultation exists. Commission officials have not (yet) solved the Hayekian problem of knowledge. I am sure the concours will get us there someday.
12. You need to put your concerns down on paper. Don't sit in your office/zoom call grumbling about things. Officials can't refer to problems or solutions that are sitting only in your head. They really are not telepaths. And if you don't put your thoughts down on paper and submit them, the Regulatory Scrutiny Board are never going to be able to refer to the source to a non-existing concern as the basis for a preferred policy option. Problems dreamed out of thin air are going to be dropped quickly.
13. Try and use plain English. It is not as hard as the many public consultation submissions suggest. Showing charts and tables is often good.
14. Be civil and polite. Decency makes you look good, even when you disagree with the premises being put forward.
15. Don't go off to the deep end. Have a friend look it over for a political sanity test. For example, if you want to deny man made contribution to climate change, just realise your feedback is going to be sitting in the same green ink pile as David Icke's submissions.
16. Don't use PR slogans and use evidence. Slogans show lazy thinking or cult membership.
17. If you disagree with the initiative or presumptions, please say so. The too familiar "I welcome and support the Commission initiative" and then criticise every aspect of the initiative, looks like it is written by someone with a split personality.
18. If you disagree, explain why, and the produce evidence. Provide a workable solution.

19. And, remember, even if it hard and rare to switch the political direction set down in the inception impact assessment or roadmap, it is not impossible.
20. Mirror back the thinking and language of the Commission. Read their own reasoning and political guidelines to them.

Effective public policy engagement is the life blood of making good laws and policies. Public consultation is an important opportunity to make your voice heard and influence the process. Don't be silent or write gobbledygook.

A 10 point checklist before you start your campaign journey

24th April 2019
Political Communication

I just re-read Chris Rose's campaign bible chapter on 'How To Begin'. He recommends a method of designing a campaign that many will find alien. Instead of jumping in, there is a detailed screening exercise before the outward facing action starts.

Set against this pre-departure the checklist, most campaigns, both NGO and corporate, fall far short. It helps explains why most campaigns don't land up where they planned to be.

A 10 point pre-departure checklist

First, you need to understand what motivates your audience.

The best way to do this is to split your time between listening and sending information. You have to listen to your target audience, your allies and opponents.

And, before launching, and throughout the campaign, you need to check back to see if it makes sense.

Few do this. The pre-launch testing, re-calibrating are techniques used by few. The too common cult-like messaging session is still standard. They tend to land up being sessions amounting to affirmations of faith.

Second, you need to Keep it Simple. Too many campaigns messages need a PhD to understand what's being said. After all, if you use language that only you can understand, you can't be surprised that it is only you who supports your message.

Third, the best communication "raises awareness, that ensures alignment, brings about engagement and secures action.

To do this, you need to highlight a problem, identify someone who is responsible, and provide a solution." You need to provide all three.

*Campaigni*ng is:

- Solutions focused
- Driven by Events as events galvanise people.
- Practice Simplification

Campaigning is not:

- Education
- A set of arguments
- Complexity

Fourth, too many "want to educate others to see the issue in the right way before accepting their support." You need to ignore these people. Personally, I'd recommend keeping them locked away for the duration of the campaign. These people will go off script too quickly. They'll look to educate, convert, and in their eyes, save the target audience when they have the chance. Your target audience will run a mile, and you'll throw away their support.

Fifth, you need to be "opportunistic, not in terms of their beliefs and values but in terms of reaching audiences". Many reject opportunism. I don't. I've spoken to a group of self-declared libertarian MEPs on the evils of fisheries subsidies, and to former Communist bloc States on the chance to harness energy sources from Canada.

The key is to reach your target audience. I've never minded that if a politician supports you for only one vote, just as long as they vote for you on the vote that counts. I even helped persuade Nigel Farage to turn up to vote in the Fisheries Committee to ban discards. In a tight vote, every vote counted. His vote helped.

What's your essential communication components – a useful checklist

Rose provides a useful checklist:

- Channel – how the message gets there
- Action – what we want to happen (and what the audience is asked to do)
- Messenger – who delivers the message
- Programme – why we are doing it – to assess the effectiveness
- Context – where and when the message arrives, including what else is going on
- Audience – who are we communicating with
- Trigger – what will motivate the audience to act"

Sixth, I've seen too many times – in NGOs and industry – that each of these elements is guessed at, or even worse, made up on the go.

It's important to research this and be very clear about it. You can't underestimate the importance of pre-launch research. As a rule of thumb, I set aside 25% of the total budget for the initial research phase. Many think this is too much. From my experience, it's better to know before you go public that the core premises that your campaign is based on are wrong. It is better than launching and then finding out mid-campaign that the facts don't support you.

The biggest challenge is curbing the enthusiasm of colleagues to go with a 'great idea', and resist the research phase for an 'obviously great idea'. This zealotry is a good indicator that the research won't provide the evidence to support your campaign. And, whilst it is hard to tell people the bad news, it's far better to do it before you have launched.

Every time I have stopped a campaign because the research shows the facts did not support the campaign I've been accused of vile crimes akin to infanticide. I have been subject to pressure to let it pass this one time. If you do let it pass, your Achilles heel will reveal itself at the very worst time, and sink all your good work. It will probably set back your reputation by 5 years.

If you speak to you your target audience, at the wrong time, in the wrong tone, and through a channel your audience does not know exists, you have more or less guaranteed from the start that your communications are about to fail.

I wish such foolishness was rare. The vital research step is often ignored. There are few journals of record that politicians and officials read – FT, The Economist, and the National Geographic – whose coverage is influential.

Seventh, perhaps the most useful lesson is to do "what works for your target audience, and not what works for you". If you want to win, you need to get people to back you on their terms, rather than on yours. Most organisations, both NGOs and industry, find it hard, if not impossible to do this.

For me, this inability to quiet the ego is the reason most campaigns, both NGOs and corporate, fail. Self-vindication is not a winning idea.

Eighth, I dislike the word 'strategy'. It is a much-abused word. It is often used as a broad cover for a set of actions, often bundled together erratically, with the hope and prayer, that it will lead to some outcome.

Rose defines it in the proper sense as "changing the prevailing forces so that you can win. The strategy is your map change: more than a conventional navigation, one that doesn't just traverse the terrain of society, but reshapes it. Your communication strategy and engagement tactics need to take supporters on a journey too."

Ninth, after you come up with the idea you need to develop the strategy. This involves testing the messages and evidence. After this, you need to prepare an activities and resources plan. This should be a cautious costing. I recommend over budgeting by 25%. There is often project creep. Better to be cautious from the start.

When this is done, you need to get the project signed off. After it is signed off, usually by more senior people, you roll out the campaign. You need objective criteria in place to track the success of your campaign. It's important to build in the latitude to revise. Finally, you need to build in checkpoints to see if you need to go on, adapt, or stop.

Finally, the greatest challenge is you'll be so bought into the strategy, that you'll not be able to identify the (huge) gaps. Self – belief and ego will cloud reality.

I find it helpful to hand the draft strategy to a seasoned professional to dispassionately review the strategy, identify the weak spots, and be brutally honest with you. This only strengthens the final product. Most people don't do this. They dislike the risk of their ideas and plans being torn apart. These people should get out of campaigning.

Lobbying in practice – Public Consultation –

28th January 2020
Lobbying

Post 2

Public Consultation

Since 1st March 2017, the Commission has a one-stop-shop for the public's contributions to the Commission's law-making process.

https://ec.europa.eu/info/law/better-regulation/have-your-say

Initiative	**Duration** feedback
Road Map/Inception Impact Assessment	4 weeks
Initiatives with Impact Assessments	12 weeks
Consultation after proposal published	8 weeks
Draft secondary legislation	4 weeks

Feedback for 3rd Countries

WTO TBT

The EU provides third countries with chances to intervene. Legislation which could potentially contain technical barriers to trade is submitted at *draft* stage to the other WTO Members

Feedback is 60 days for secondary legislation, and in general 90 days for ordinary legislation.

Below are some cases of secondary legislation and ordinary legislation going through the TBT notification process.

It is open to debate whether the feedback the influence of such feedback from third countries.

You can find ongoing notifications here.

Secondary – Procedure RPS

Case 1: 14th update to the CLP (link)

Commission Draft Regulation: 12 December 2018

WTO Date of notification 12 December 2018

Deadline for comments: 10 February 2019

Deadline for comments: 60 days from notification

Secondary – Procedure Implementing Act

Case 2: Draft Commission Implementing Regulation on technical standards for the establishment and operation of a tracing and traceability system for tobacco products

Proposal: 4 September 2017
WTO Date of Notification: 12 September 2017
Deadline for comments:11 November 2017
Deadline for comments: 60 days from notification

Secondary – Procedure Delegated Act

Case 3: Draft Endocrine Disrupters (Biocidal Products) : 15 June 2016

WTO Date of Notification: 23 June 2016
Deadline for comments: 31 August 2016
Deadline for comments: 60 days from notification

Case 4: Proposal for a Directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) (Recast) 31 December 2008

WTO Date of Notification: 3 February 2009
Deadline for comments: 11 April 2009
Deadline for comments: 67 days from notification (90 days)

What maps do lobbyists need to use

3rd June 2018
Political Communication

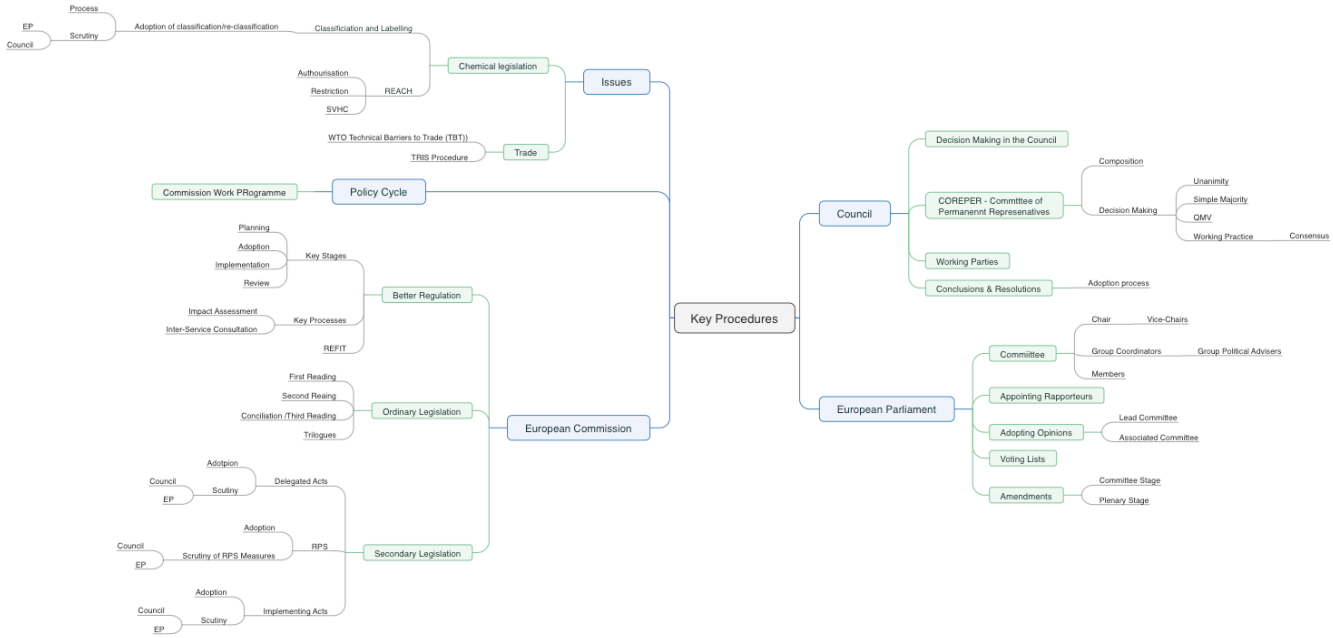
I think it is hard to get to where you want to be if you are using the wrong map.

This is certainly the case in lobbying. If you driving in the wrong direction to where you need to be, the chances of you getting to where you want to be are at best slim.

An easy way to get to where you want to be is to follow the pre-set processes set down by the law and rules of procedure. Too often, too many people go out on their own without using a map, guide or GPS. The results are usually the same. They don't get what they want.

As a lobbyist, I think there are some maps you need to use. You can put them in your memory, back of your pocket, or file them away for when you need them. I use around 30 legislative maps and 20 campaigning maps. These are just written down models. They act as a useful checklist. I write them down as I don't have a photographic memory with perfect recall.

Below is a mind map of some key processes for chemical issues. These are taken from an excellent guide 'Handbook of EU Processes Flow Charts' prepared by PACT European Affairs.



A model for winning legislative campaigns in the EU

18th April 2016
EU

I thought it was time that I write out the model I use for winning legislative political campaigns in the EU. I have been asked to write it before, but I now have a lot of time on my hands, so got around to it.

I am sure there are many holes in it. I'd welcome hearing from you.

The ideas behind it are not complex. They are born from nearly 20 years working in Brussels working on passing or campaigning to influence EU legislation. During that time, I have looked to refine the model, take on board what works, and more importantly, discard what does not work. As a model, it is tested with each new campaign, and the model is constantly refined. If it does not work, I'll get rid of it.

I could summarise the approach as "speaking to the right people, at the right time, in language they understand". I'll go into more detail in four sections:

- What game are you playing
- Value Based Communications
- The key people
- Understand the game you are playing

What game are you playing

I am always curious if people campaigning or lobbying on a proposed law are in the business of winning or whether they want to convert people. There is a big difference.

If you want to win, at the end of the day, you want your proposal (or amendment to it) to be adopted. You don't really care whether the majority of politicians voting for your proposal (or officials if it is delegated legislation) support your position, let alone believe in it. All you care is that for that one moment in time when they come to vote on it the majority you need back your position.

I have seen politicians and officials back an option I have campaigned for knowing full well that many of them opposed it personally. But, events were engineered so that at the right time, on the right day, they voted for the right thing.

On the other hand, I have seen many lobbyists, campaigners, companies and NGOs wanting to convert people to their position. I find the practice of converting people to be time and resource consuming. Given so many NGOs and companies are in the business of converting non-believers and opponents to their position I am sure it must sometimes work. I just guess that my not seen visible signs of mass conversions of non-believers and opponents is a sign of being general sceptical and broadly agnostic.

But, the general practice of "conversion or nothing" dominates Brussels, and I think most political campaigns. It perhaps explains why so few campaigns deliver. It's like Jehovah Witnesses going to the Holy See and being surprised how few, if any, of the flock of Rome, admit the errors of their ways and switch sides. In reality, many companies and NGOs are asking non-believers and opponents to accept that they are wrong, usually on an issue that is deeply important to them as an individual, and publically convert. That the issue is usually sold to them in terms that amounts to as nothing more sophisticated as " you can't do that because it will hurt my profits", or "we need to stop modern industrial production, even if the technology does not exist to replace it" – here I basically paraphrase opening gambits I have heard from industry and NGOs – it is not hard to understand why the modern business of conversion is a hard slog.

Value Based Communications

I have written about Value Based Communications before (please see here).

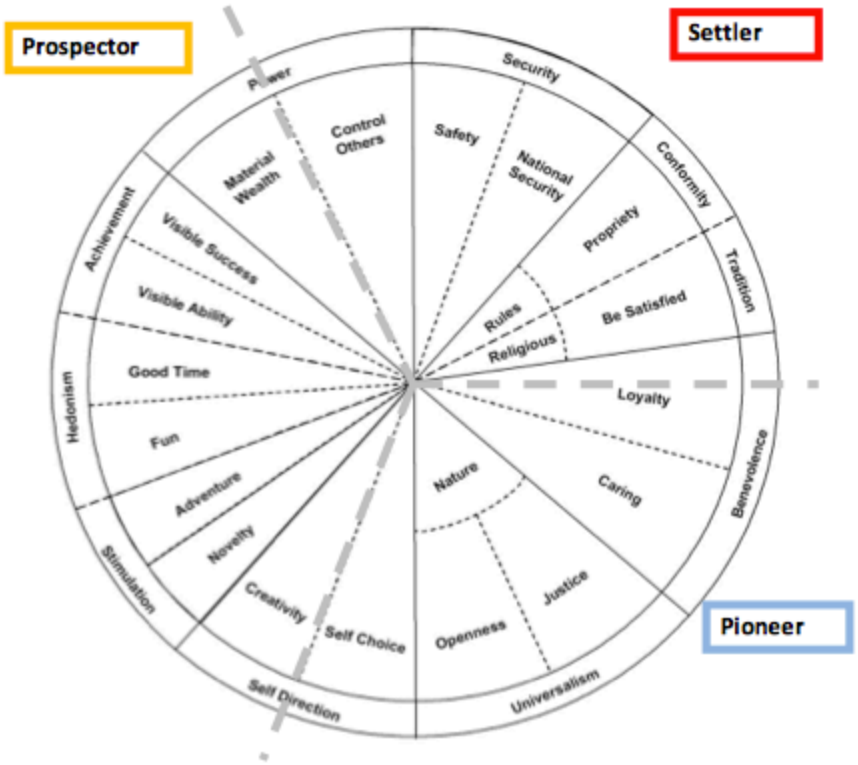
If it worked for Ronald Reagan, Bill Clinton and Tony Blair it can work for you. It works for Greenpeace and Toyota. Yet despite working, a lot of people don't like it for what I can see as two reasons.

First, they think communicating to people in ways that makes sense to the target audience as manipulative. Second, a lot of people don't like idea of changing the story they tell to different groups of people.

First, the business of political persuasion could be seen as manipulation. It is about putting the best set of ideas forward to a given individual that will persuade them. As people seem to have one of three value sets (Settlers, Prospectors, and Pioneers) who look at the world in very different ways, the only hard part is to re-articulate your case in language that resonates with each of those three groups. It perhaps explains why many people use the same arguments to Social Democrats, Christian Democrats, Liberals, Conservatives, Greens, Communists, nationalists and fascsicts. That this assortment of political interests look at things very differently shows that it is vital to adapt your story for these political traditions.

Second, only very unsuccessful salespeople use the same story line all the time. Why people buy into something is individual. Not understanding what makes those people tick you are trying to sell to, and adapt your case and language to support that case, is at best lazy and at worst politically suicidal.

I find the chart below helpful in that it provides examples of what drives people in Settlers, Prospector, Pioneer groups. The language and case you need to put to these groups is very different to win them over is very different. You can of course use your standard presentation with the same language to everyone, but please don't be surprised if it does not influence many people.



I have used this on some campaigns. The most dangerous side effect I found that a very broad coalition of politicians supported the issue, for a whole variety of reasons, and most of the time not for the same reasons that the client backed the campaign.

I recommend anyone to read Chris Rose's book "What Makes People Tick" and the excellent analysis from Pat Dade at Cultural Dynamics.

Key People

I used to think that on any given issue on a piece of EU legislation 500 people count. I have just looked over a very detailed

list of the key decision makers across the EU 28 on an issue I have followed closely for a long time. To my surprise the number is 228 people.

That list includes:

- Commissioners
- Cabinet Advisers
- Key officials in the Services, including drafters, legislative team, inter-service steering group
- MEPs working on the issue
- Key advisers to those MEPs
- Ministers
- Key political advisers
- Permanent Representative officials
- Key Directors and officials in national Ministries
- Active and influential journalists in the EU 28

Each and every one of those people has a name, email, phone number, mobile number, and postal address. Each and everyone of them has a general position on the broad issues, and sometimes specific positions on specific issues. For key people, specific argumentation points will of course be developed in advance, and even have rehearsed. Understanding from where they are coming from and adapting your conversation to win them over is essential.

Whilst having the list in advance, please bear in mind that the list will alter for two main reasons. First, some key players will appear during the process, that were at the start of the process unknown. You can even sometimes engineer for new players to enter the process if you think that will assist you. Sometimes a President may overrule a Minister after some well targeted media. Second, governments in an EU of 28 are having elections, and Ministers come and go. Key allies or opponents one day may not be in power the next day. The list is of course a living list.

Also, depending where a proposal is in the process will be vital. At the start of a proposal, the Inter-Service Group and Cabinet leads will be vital, but the same people will have little or no role when the final conciliation meeting starts.

Understand the game you are playing

Europe deals with two main types of legislation: ordinary legislation (co-decision) and delegated legislation.

The process for the adoption and passage of both types of legislation are very different. The people who make decisions and by why what majorities are very different. All too often campaigns use a reverse read across and hope what worked once before will work again. This in my view takes faith healing to a new level of blind adherence. If you'd don't read the correct map (the process and the rules for your specific proposal) it is very likely that you will get lost and not turn up on time, if it all.

All too often, campaigns will blame the system as being unfair when they get lost and loose. In reality, what has happened is that the campaign has not looked at the right map, or not even picked up a map at all. In retrospect, their loss is not a surprise, it is more just a foregone conclusion.

Finally, the opportunities for planting seeds that lead, over time, to new proposals and maybe laws are plentiful. Yet again, few people take the time to plant the seeds. For one NGO I worked, a report we published that provided a template solution to a seemingly intractable problem, which provided substantive, practical and real life solutions, was co-opted in large part by the Commission and tabled in a proposal. This long-term thinking requires you to delay the instant gratification of instant changes, and rather allow ideas to blossom over years and have them become mainstream and co-opted by others. The results are usually more positive and longer lasting. It's better to help at the very start design a system than to campaign and alter a component of the overall solution.

Lattice Work

I hope that this lattice-work of campaign approaches is clear and provides you with some ideas on how not to turn up late and influence the adoption of legislation.

EU Better Regulation in 10 easy Charts & Checklists

6th August 2017
EU

The current guidelines, 19.5.2015, are here. They are 91 pages long. They are supported by a Toolbox (here) of 414 pages. This rule book has been updated. It has been transmitted to the European Parliament and Council. It is now 90 pages of detailed guidelines and supported by a 500 page Toolbox.

I would recommend that you read this Manual. But, in case you don't want to, I have listed some of the most useful checklists and charts.

In Praise of Better Regulation

I have been an isolated supporter of 'Better Regulation'. I think it is the most revolutionary and positive action of the Juncker Commission.

There is a virtue in the certainty in the preparation and development of policy and law. Bruno Leoni, in Freedom and the Law, writes about the importance of officials discretion being limited by clear rules..

The Guidelines provide a clear set of rules that any official can follow. The Guidelines are so clearly written so there should be no reason why they are not followed.

I welcome two main aspects of the Guidelines.

First, by codifying good practice it limits administrative discretion in developing new rules. It places weaker restraints on the exercise of political discretion by Commissioners, and very few on elected MEPs or Member States. Politicians and governments, as a broad class, are reluctant to have their hands tied, let alone follow basic good practice.

Second, it opens up European law making to public scrutiny. Now there is a lot of scrutiny. I am not sure how many people login into to it. I check it out every week. You can find it here.

Better Regulation is about 'designing EU policies and laws so that they achieve their objects at minimum costs. …. It is a way of working to ensure that political decisions are prepared in an open, tranpsranet manner, informed by the best available evidence and backed by the comprehensive involvement of stakeholders'. Why anyone could be against this is beyond me, but there are many who are.

When to follow and not

Officials have to follow the steps laid out in the Guidelines. The Toolbox provides additional guidance. The Toolbox is only binding if "expressly stated".

There are times when the Guidelines may be by-passed. These include:

- social partner agreements (see Art.155 Treaty),
- a political imperative to move ahead quickly,
- an emergeny,
- specific deadlines in legislation, or
- a need to respect security related or confidential information

If officials want to apply an exception they need to ask for this at:

1. When the initiative is getting political validation

2. Permission frm the Secretary-General and First Vice-President

The Guidelines are meant to be read by all 'officials involved in regulatory activities.' It would be interesting to know how many have.

The greatest weakness to Better Regulation is political will and time at the very highest levels of the Commission to follow and implement it. A First Vice-President who is clearly so busy and active must have little time to pick political fights with his fellow Commissioners and high ranking officials who would rather pre-determine the policy outcome from the very start than go through an exercise that may deliver results they do not like.

Key Checklists and Charts

Below I have gone through the new Guidelines and Toolbox and pulled out the 10 most useful charts and checklists.

1. **When is Political Validation Required?**

See: Box 2. Scoping, political validation and interservice work

• Political validation is required to move beyond the informal consideration of a possible initiative and to start the substantive prepatory work including engagement with stakeholders.

• The level of political validation depends on the nature and importance of the inititiave. "Major initiatives" should, in principle, be entered into Decide at least 12 months prior to adoption by the College. They must be validated by the lead Commissioner, relevant Vice-President and the First Vice-President before being accepted to be included into the Commissions' planning. "Other initiatives" should be validated by the lead Commissioner or by the Director-General of the lead DG as appropriate.

• Political validation must be understood as giving the green light to start the substantive preparatory work. It should not be interpreted as a decision on a particular initiative or course of action that prejudges the outcome of any impact assessment process, stakeholder consultation or later political discussion in the College.

• For major initiatives and for evaluations (including fitness checks), once political validation is granted, roadmaps or inception impact assessments must be finalised and published as quickly as possible. They explain to external stakeholders what the Commission is considering and allow them to provide early feedback.

• Roadmaps are used for initiatives which do not require an impact assessment. The reasons justifying the absence of an impact assessment will be included.

• Inception impact assessments are used for initiatives subject to an impact

assessment. These set out in greater detail the description of the problem, issues related to subsidiarity, the policy objectives and options as well as the likely impacts of each option.

• A roadmap is prepared for each evaluation or fitness check. This specifies the context, scope and purpose of the evaluation and outlines the proposed approach.

• All roadmaps (including for evaluations and fitness checks) and inception impact assessments are published by the Secretariat-General on the Commission's website12 so that citizens and stakeholders are informed and can provide initial feedback (including data and information they may possess) on all aspects of the intended initiative and where applicable its impact assessment.

• Evaluations, impact assessments, stakeholder consultations, policy proposals and implementation plans must be discussed collectively by the services13 within an interservice group. It is important that all services with an interest participate actively in the interservice work from the outset, particularly those DGs with specific expertise (e.g. competitiveness and innovation, SME impacts, economic, social impacts, environmental impacts and scientific/analytical methods).

• The launch of the interservice consultation must be agreed politically (in a similar way to the validation of new initiatives). In addition, where an initiative is supported by an impact assessment, a positive opinion of the Regulatory Scrutiny Board is required in order for the initiative to be presented to the Commission for decision.

2. Who validates for what & the implications

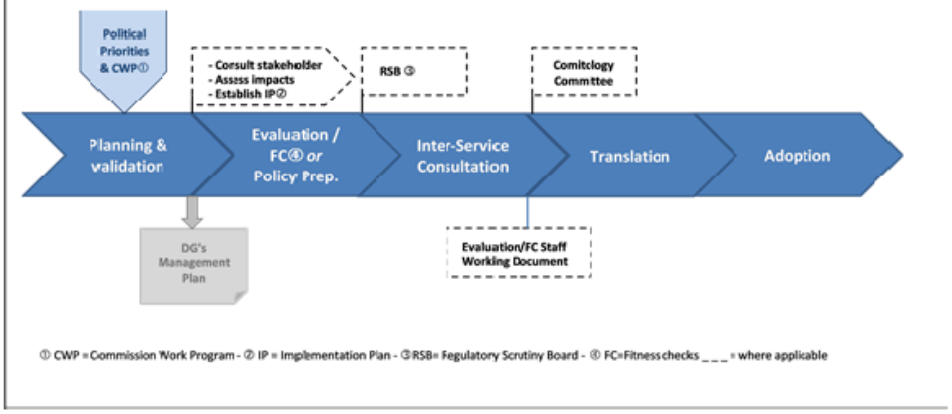
3. The Planning and Validation Process – A schedule

Table 1. Political validation of initiatives and linked requirements

Initiative type		Who validates?	Roadmap or inception IA?	ISG needed ?
"Major" initiatives (*Decide entry at least 12 months prior to adoption*)	All major initiatives	FVP & VPs & Commissioner in close collaboration with the President	Yes	Yes
"Other" non-major initiatives (*Decide entry*)	Initiatives which are neither "major" nor evaluations or fitness checks *(Decide entry at least 3 months before adoption)*	Commissioner	No	No
	Evaluations & fitness checks *(Decide entry at*	DG (*Management plan*)	Yes	Yes

Initiatives handled outside Decide	DG	No	No

Figure 1: Planning and validation in the policy development process



4. The Key Questions an Evaluation Must Answer

1. What is the current situation?

2. How effective has the EU intervention been?

3. How efficient has the EU intervention been?

4. How relevant is the EU intervention?

5. How coherent is the EU intervention internally and with other (EU) actions?

5. Key Timelines for Public Consultation

6. What documents go to the Regulatory Scrutiny Board?

6.1 Impact Assessment

What?

Note signed by the Director General of the lead DG addressed to the chair of the RSB.

? Draft IA report (SWD).

? IA summary sheet accompanying the IA report (SWD).

? Minutes of the meeting of interservice group that has been preparing the IA report immediately prior to submission of the IA report to the RSB.

? Links to where important underlying reports or studies can be found which underpin the IA report.

? Underlying evaluation SWD, if this evaluation has not been scrutinised separately by the RSB.

Mandatory open, internet-based public consultation:	*How long?*	*When?*
• Initiatives with impact assessments • Evaluations • Fitness checks	Minimum 12 weeks[129]	Decision on case-by-case basis
• Consultative Communications • Green Papers		After adoption by the Commission
Stakeholders must be enabled to give feedback on:	***How long?***	***When?***
• Roadmaps for evaluations and fitness checks	4 weeks	After publication
• Roadmaps, inception impact assessments	4 weeks	After publication

When

? The lead DG should reserve a slot at a future meeting of the RSB at which the IA report will be discussed. In general, **the slot should be reserved at least 3 months before the RSB meeting**.

? This slot should reflect the envisaged timing of the political initiative, the time needed to adapt the IA report in light of the Board's opinion(s) and the time needed to complete a formal interservice consultation and formal adoption by the College.

? The draft IA report should be submitted to the RSB at least 4 weeks before the RSB meeting where the draft IA report will be discussed.

? In a few exceptional cases, the RSB may decide that the draft impact assessment report does not need to be discussed at a formal meeting of the Board but can be dealt with via **written procedure**. This can only be decided on a case-by-case basis once the draft IA report has been submitted to the RSB and will depend on the quality and lack of complexity of the case at hand.

Re-Submissions

? Where the RSB issues a negative opinion, the lead DG will have to incorporate the Board's recommendations into a revised IA report, to discuss those changes with the ISG and to submit a revised report to the RSB.

? The RSB will aim to issue a revised opinion within 4 weeks following resubmission. In most cases, the opinion will be issued following a written procedure. However, the RSB may wish to hear the lead DG again in a meeting. In such cases, the RSB secretariat will organise an appropriate slot in consultation with the lead DG.

What?

Note signed by the Director General of the lead DG addressed to the Chair of the RSB.

? Draft evaluation SWD/fitness check report (SWD).

? Executive summary of the evaluation SWD or fitness check report.

? Minutes of the meeting of interservice group that has been preparing the evaluation report immediately prior to submission of the draft evaluation report to the RSB.

? Quality assessment discussed and agreed by the ISG.

? Any report prepared by consultants (where relevant).

When?

The lead DG should reserve a slot at a future meeting of the RSB at which the evaluation/fitness check report will be discussed. In general, **the slot should be reserved at least 3 months before the RSB meeting**.

? In line with the "evaluate first" principle, the fitness check report or evaluation SWD should usually be reviewed by the RSB ahead of the submission of the corresponding impact assessment.

? The draft evaluation/fitness check report should be submitted to the RSB at least 4 weeks before the RSB meeting that will discuss the draft evaluation SWD or fitness check report.

? In a few exceptional cases, the RSB may decide that the draft evaluation report does not need to be discussed at a formal meeting of the Board but can be dealt with via written procedure. This can only be decided on a case-by-case basis once the draft evaluation SWD or fitness check report has been submitted to the RSB and will depend on the quality and lack of complexity of the case at hand.

Follow up

The lead DG is expected to incorporate the Board's recommendations into a revised fitness check report or evaluation SWD and to discuss the changes with the relevant ISG.

? A negative opinion does not prevent the launch of an interservice consultation on the fitness check report or evaluation SWD. However, the lead DG may wish to submit a revised SWD or report to the RSB. In such cases, the Board will aim to issue an opinion within 4 weeks usually by written procedure. In some cases, the lead DG may be invited to a meeting with the RSB which will be

8. Initiatives for which the need for an IA should be assessed

1. New legal acts

Revision of existing legal acts
Recasts of existing legal acts
Non-technical repeal of existing legal acts77
Delegated acts (Art. 290 TFEU)
Implementation measures (Art. 291 TFEU)
Transposition of international agreement into EU law78
White papers
Policy communications
Action plans
Recommendations

Type[81]	Reason
Administrative decisions	Lack of significant impact (or relevance for policymaking)
Enforcement of EU law (competition law enforcement cases, infringement decisions, etc.)	Lack of policy alternative as decision parameters are set by existing EU (case) law.
Trade defence cases and enforcement action under international trade rules	Lack of policy alternatives
Budgetary procedures and measures, Financing Decisions and programme management decisions	Lack of policy alternatives/ex-ante evaluation not required

Recommendations for the negotiation of international agreements.
Social partner agreements pursuant to Articles 154-155 TFEU79.
Financial programmes (i.e. all basic acts for spending programmes and financial instruments)

9. Initiatives for which no automatic need for an Impact Assessment

Commission reports /scoreboards	No policy decision, lack of impacts
Communications to the Commission	No policy decision, lack of significant impacts
Economic governance: recommendations, opinions, adjustment programmes	Specific processes supported by country specific analyses
Green papers	No policy decision, lack of significant impacts
Legal alignments	Lack of policy alternatives / no significant direct impacts
Legal codifications	Lack of policy alternatives / no significant impacts
Staff working documents	No Commission decision, lack of significant impacts
Conclusion, signature and provisional application of Bi/multi-lateral agreements with Third Countries: conclusions signature, provisional application and/or prolongation of existing protocol.	Lack of policy alternatives given finalisation of negotiations

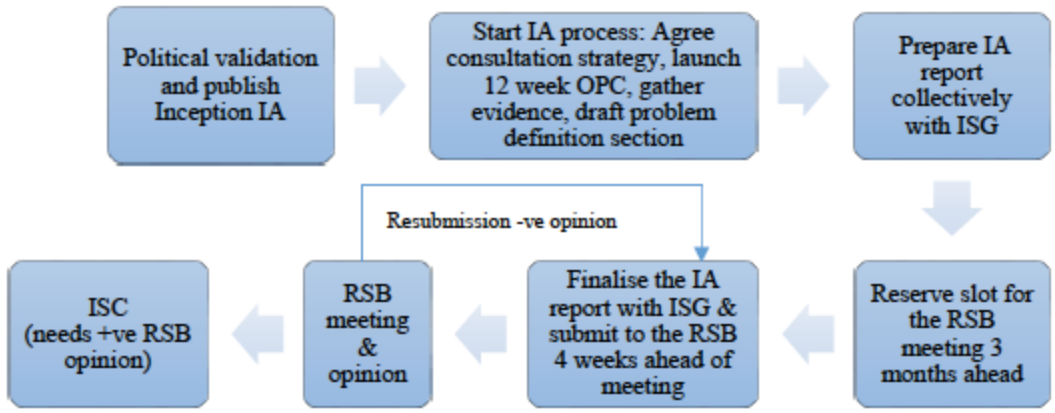
9.2. Do you need an Impact Assessment when an EU Agency is Involved?

10. Key Steps ad Requirements for an Impact Assessment

main policy-design work and prepare an IA-like document, no Commission IA is necessary a priori.

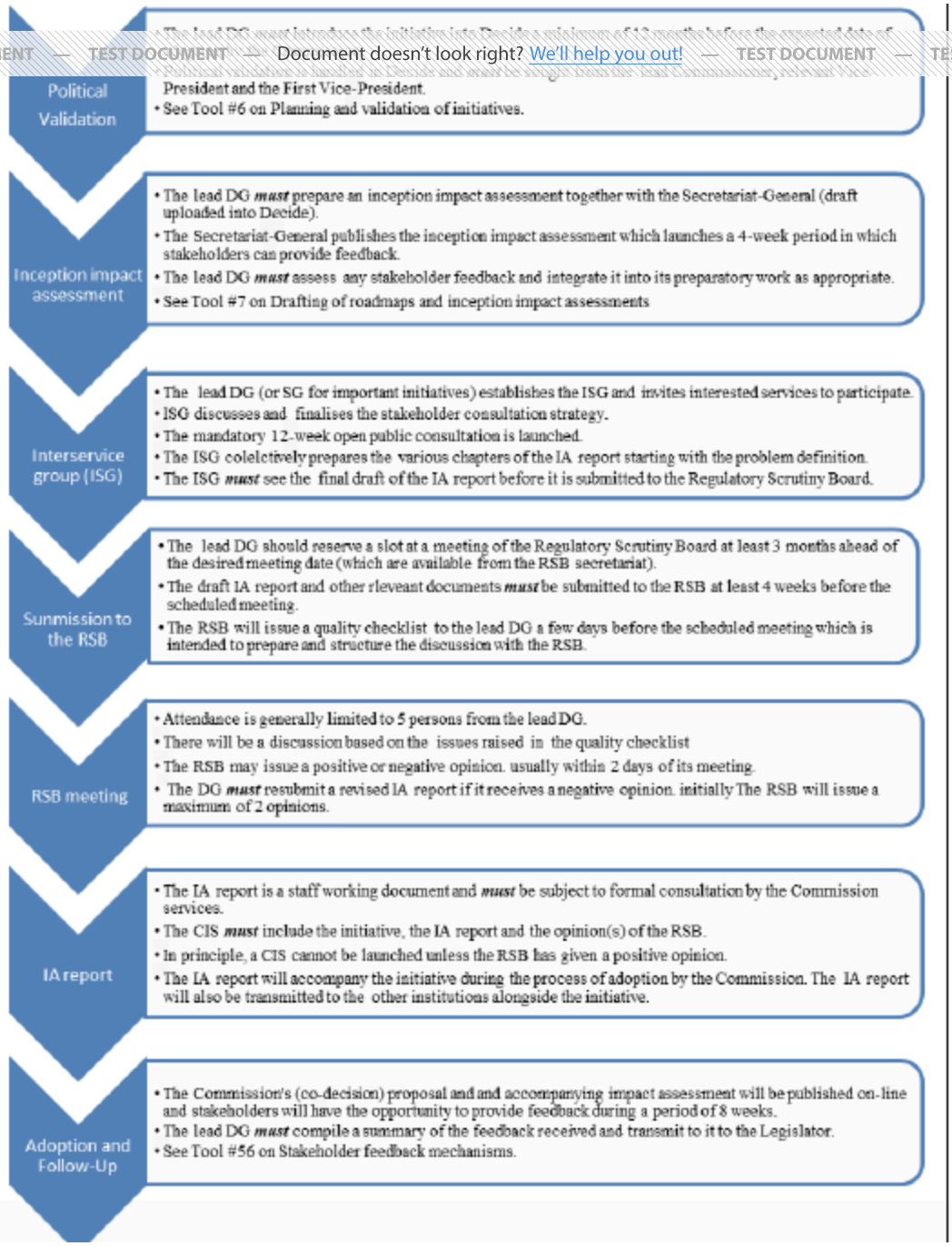
- The Commission's internal rules on better regulation and impact assessment do not apply to EU agencies[82]. However, the lead DG should ensure that the agency's analysis broadly meets the Commission's consultation and IA standards and takes responsibility/ownership for the quality of the assessment.
- The lead DG should (in consultation with the Secretariat-General) consider whether the Commission's initiative would benefit from further analysis and a complementary IA due to its complexity, or the significance of the expected impacts or where the Commission is likely to deviate from the advice of the relevant agency or indeed where the Agency's work does not meet the Commission's usual standards.
- During policy preparations, the lead DG may decide itself or be asked by the SG or other Commission services to supplement the agency analysis if duly justified and/or – in consultation with the SG – to undergo scrutiny by the Regulatory Scrutiny Board. In the latter case, the lead DG is responsible for submitting a draft IA report to the RSB in accordance with the better regulation Guidelines and this Toolbox.

Box 1. Process to prepare a typical impact assessment



The time needed will depend on the evidence which is already available, the need to rely on the results of study contracts etc. Typically up to 12 months although can be significant shorter.

10.2. Process Chart for the the typical Impact Assessment



Inter-service consultation – the basics

25th February 2018
EU

I was sitting down with some people who are working on a new proposal the Commission hope to put out the door before 29 May cut off.

I asked where they were in the process. It had gone to the Regulatory Scrutiny Board and passed with flying colours. In a few days a legislative proposal would be drafted and sent up for adoption.

On the next step, before the proposal sent to the EP and Council, most people get blurry and haze over.

Inter-service consultation

The procedure where the Commission adopt the legislative proposal is known as 'inter-service consultation".

I think it is the most important part of the whole legislative process. I do so for one very simple reason. On most files, whatever the Commission puts out the door, finally gets adopted without fundamental changes. In my experience, despite all the money interests spend lobbying the European Parliament and the Member States, 85%-95% of the Commission's proposal goes through unaltered.

Surprisingly, a lot of interests ignore inter-service consultation. I think this is a mistake.

If you can make a difference, this is the best time to engage.

Now, there is an issue that this process is not public. But, with Better Regulation, you must have recurring amnesia to be caught out surprised with a new major initiative.

MindMap

I have tried to summarize the process in a mindmap. I hope it is useful.

A Case Study Blue Fin Tuna – CITES

In my time at WWF, I worked on the CITES listing of Blue Fin Tuna. Monaco has tabled a proposal for protecting this endangered species to CITES. The EU needed to work out if they would support the proposal.

CITES sits with DG Environment. They wanted to back the motion. DG MARE opposed.

A few of us campaigning on the issue thought that this issue deserved some more coverage. The FT and other news outlets picked it up and covered the process. We did not want DG MARE to block DG ENV.

Source: FT (link)

I don't think a lot of Commission officials, Heads of Cabinets and Ministerial advisers appreciated the degree public interest and scrutiny. More than one expressed their frustration to me. This after all is meant to be a secret process they would plead.

I naively disagreed and the publicity paid off. DG ENV won.

What does the process look like?

At the time, I was fortunate. I had worked in DG ENV and learned that the best way to to adopt a proposal is to have a

Stanley Pignal in Brussels AUGUST 21, 2009

Support is growing in Brussels for a commercial ban on bluefin tuna amid recommendations from policymakers to add the fish – prized by sushi lovers – to a list of endangered species.

The recommendations are included in a draft document prepared by the European Commission's environment section. This will form the basis for the 27-member European Union's common position ahead of the next meeting of the Convention on International Trade in Endangered Species.

"From a scientific and technical point of view, the criteria for the listing of Atlantic bluefin tuna [as an endangered species] appear to be met," the draft states.

rudimentary understanding of how the Commission adopt their proposals.

Fortunately, the Commission spell out the mechanics of adopting proposals clearly.

There is a helpful handbook from the Commission on their 'Working Methods'.

Loading…

COMMISSION EUROPÉENNE
SECRÉTARIAT GÉNÉRAL

Direction A – Greffe

C(2014) 9004

Bruxelles, le 11 novembre 2014

PROCÉDURE ORALE

TEXTE EN

the_working_methods_of_the_european_commission_2014-2019_november2014_en

Communication à la Commission relative aux méthodes de travail de la Commission

I realise at times that officials may not follow the procedure with a zeal, but knowing them helps you call out errors, and maybe even influence things for the better.

The adoption procedure is in two distinct steps.

First, there is consideration by the Services. The Services are consulted on the the draft legal text, the impact assessment together with the opinions of the Regulatory Scrutiny Board.

Communication de M. le PRESIDENT

The second step is the political scrutiny by the Commissioners. Here the College of Commissioners adoption by written or oral procedure.

Adoption by written procedure requires all services to give a positive position during the ISC. Any negative opinions must be lifted via bilateral negotiation for adoption by written procedure to proceeed.

Step 1

The Commission use an electronic system called "CIS-Net".

The lead department needs to consult the following:

- Departments with a legitimate interest in the proposal

The following department usually have to be consulted:

Cette question est prévue à l'ordre du jour de la 2105ème réunion de la Commission le

- Legal Service
- Sec-Gen
- Human Resources
- Budgets
- OLAF
- Communications

If the lead Department does not follow the correct procedures, the Sec-Gen can intervene and suspend the procedure until the errors are rectified.

The Departments can say:

- No Opinion/ No Answer
- Positive Opinion
- Positive Opinion with comments
- Negative Opinion

The lead department then works to incorporate the changes.

Who is involved

There are not too many people involved. Those engaged in the the proposal come from:

- Inter-service Group
- Director Generals
- Chef de fiche – Cabinet Officials working on the file
- Heads of Cabinet
- Commissioners

In practice, you are dealing with around 20 people.

Finding out who follows the file in the Cabinet is easy enough. Their officials portfolio are posted on-line. However, double-check that they are still there – there is a high turnover.

The InterService Group is harder to find., but you need to find out who they are. They hold the power of the pen.

The rest are easy to find out. Their names are all public.

The trick is only a very few people are interested. As a rule of thumb, it is around 20 people.

When an agreement is reached at the Service level the the file is given over to political validation.

Most of the time the Commissioners agree with the proposal and there is now disagreement. Rarely there is a vote in the College, but it is very rare.

If they can't reach an agreement, the Commissioners will go several rounds looking to reach an agreement. After a few rounds, the President's Cabinet will step in to reach an agreement. On Blue Fin Tuna CITES listing, the internal wrangling went on over the summer. The Director-General of DG Environment got annoyed that his Commissioner was ignoring his advice. His Commissioner won the day.

Before you start lobbying, here are 70 questions to answer

1st May 2017
Political Communication

I just re-read some excellent political campaign advice from Chris Rose. His advice is well worth listening to. He's the man behind Greenpeace's Brent Spar win.

3 Stories

Chris recommends having 3 stories for your campaign

http://threeworlds.campaignstrategy.org/?p=279

1. "The Popular story – understandable (test it out) by your relatives, neighbours etc.. The default story to use if in any doubt, and the only one to use with 'the public'. No jargon.
2. The Professional story – the way the policy community see it. Jargon usually required here. This is the default internal campaign language but must not be allowed into the general public or media domain except maybe with trade/ professional press or policy community blogs etc.
3. The Political story – what's in it for me as a politician (or CEO etc). This is not to be confused with the Professional story. Top decision makers are not interested in your campaign goals (that only annoys them), they are interested in the benefits to them and their organisation in terms of profits, career prospects, gaining advantage, being popular, not losing their job, and so on. These are your 'benefit' selling points. See also Bryceson's Political Checklist."

My campaign checklist

My checklist evolves over time. The older I get, and more campaigns I loose and win, I deliberately try and learn lessons from success and failure. I refine the process each time.

What I know that a lot of political campaign success is down to hard work by preparation. Getting the simple things right like contact lists of the key people or knowing the process you are involved in, is vital. Too many people forget it.

The more questions below you can not answer yes to, I think the less chance you have of winning. The questions have a common question "Do you know" and all you need to do is give the answer yes or no. The more positive answers the more you have a good chance to win.

If you were going to start a legislative campaign, here is a checklist

What are you dealing with
1. Do you know what legislative process are you dealing with? yes [ ] no[ ]

Tick which is applicable

Ordinary
Delegated
Delegated Act
Implementing Act
RPS
Other

2. Do you know where the proposal is in the procedure? yes [ ] no[ ]

Adoption
3. Did the proposal secure a positive or negative opinion from the RSB? yes [ ] no[ ]
4. Do you know how the proposal went through ISC yes [ ] no[ ]
5. Do you know any Member States intervened in the ISC vote [ ] no[ ]
6. Did you get Member States to intervene yes [ ] no[ ]

7. Did you provide information to the public consultation to the Road Map yes [ ] no[ ]
8. Did you feed into the Impact Assessment yes [ ] no[ ]

9. Do you know where are you in the process yes [ ] no[ ]
Tick where the initiative is:
Pre-Adoption
Adoption
Legislative

Internal
10. Do you know what your campaign budget is yes [ ] no[ ]
11. Do you know who signs off on the campaign plan yes [ ] no[ ]
12. Do you know signs off on the campaign budget yes [ ] no[ ]
13. Do you know who is in campaign team yes [ ] no[ ]
14. Do you know who decides on policy yes [ ] no[ ]
15. Do you know who decides on the key decisions yes [ ] no[ ]
16.Do you have SMART objectives yes [ ] no[ ]

Background Research
17. Do you know where do the key votes stand today on your issue(s) yes [ ] no[ ]
18. Have previous votes backed you yes [ ] no[ ]
19. Do you know which politicians (MEPs/Ministers) back you yes [ ] no[ ]
20. Do you know which politicians are against you yes [ ] no[ ]
21. Do you know which politicians can be swayed yes [ ] no[ ]
22. Do you know what the vote would be if it were held today yes [ ] no[ ]

Material
23. Do you have a persuasive position paper yes [ ] no[ ]
24. Do you have persuasive communication material to back your case yes [ ] no[ ]
25. Do you have amendments and explanations for your issue yes [ ] no[ ]
26. Have your tested your positions on key decision makers yes [ ] no[ ]

Contacts
27. Do you have a working relationship with them yes [ ] no[ ]
28. Do you have their phone and email yes [ ] no[ ]
29. Do you have a local link with the politicians yes [ ] no[ ]

Commission
30. Do you know the Commission's negotiation team yes [ ] no[ ]
31. Do you know the Commission's ISC leads at Service level yes [ ] no[ ]
32. Do you know the Commission ISC Cabinet leads yes [ ] no[ ]
33. Do you know the Commissioners dealing with your issue yes [ ] no[ ]

EP
34. Do you know the Rapporteurs yes [ ] no[ ]
35. Do you know the Shadow Rapporteurs yes [ ] no[ ]
36. Do you know the MEPs Advisers yes [ ] no[ ]
37. Do you know the Group Advisers yes [ ] no[ ]

Council/ Member States
38. Do you know the Chair of the Working Party yes [ ] no[ ]
39. Do you know the Working Party officials yes [ ] no[ ]
40. Do you know the lead Perm Rep leads yes [ ] no[ ]
41. Do you know the officials leading on the file back home yes [ ] no[ ]
42. Do you know the Minister leading on the file yes [ ] no[ ]
43. Do you know the Adviser to the Minister yes [ ] no[ ]
44. Do you know key decision makers in the Ministry yes [ ] no[ ]

Opinion Influencers
45. Do you know the key journalists on the issue in Brussels yes [ ] no[ ]
46. Do you know the key think tank experts on the issue in Brussels yes [ ] no[ ]
47. Do you know the key journalists in your key countries on the issue yes [ ] no[ ]
48. Do you know the key think tank experts in your key countries on the issue yes [ ] no[ ]

Process

49. Do you understand the process you are dealing with yes [ ] no[ ]
50. Have you worked on the process before yes [ ] no[ ]
51. If not, can someone assist you yes [ ] no[ ]
52. Do you have an accurate copy of the process chart yes [ ] no[ ]
53. Do you know the triggers to move between the steps yes [ ] no[ ]

Think like a lawyer – you are looking to influence law making

54. Do you know the case your opponents are using against you yes [ ] no[ ]
55. Do you have your response prepared yes [ ] no[ ]
56. Does you have a response that speaks to politicians yes [ ] no[ ]
57. Does your response speak to civil servants yes [ ] no[ ]
58. Do you have a response that speak to the public yes [ ] no[ ]
59. Do you have indpendent evidence to support you yes [ ] no[ ]
60. Do you have a legal opinion to support your case yes [ ] no[ ]
61. Did you particpate in all the preparation phases yes [ ] no[ ]
62. Did you suppy the answers yes [ ] no[ ]
63. Did you supply the points your now rely on yes [ ] no[ ]
64. Do you have a scientific /technical case that concerns the other side yes [ ] no[ ]

Public Communication

65. Does you have a response that speaks to politicians yes [ ] no[ ]
66. Does your response speak to civil servants yes [ ] no[ ]
67. Do you have a response that speak to the public yes [ ] no[ ]
68. Does your story speak to settler, prospectors, and pioneers yes [ ] no[ ]
69. Do you have communication material available yes [ ] no[ ]
70. Do you have someone to run the publication communication work yes [ ] no[ ]

It is long post and list. The more questions you can answer immediately, the less work you will have in the future, and the more chance you will win.

Getting your issue taken up in Brussels – 7 Key Questions You Need to Answer Before You Start

16th December 2018
EU

An old friend recently called me. She wants the Commission to adopt a piece of legislation. She wants it to happen soon.

I was asked "is it doable"?

At 48 I am cautious. It is a side effect of age. Getting new legislation tabled, let alone adopted, is not for the faint hearted.

With the Commission clearing the decks for 'emergency measures' for Brexit and the last few months of this European Parliament, my gut reaction was 'no chnce for a year'. But, it got me thinking.

My rule of thumb is it takes 10 years to get your issue taken up in new law and implemented. I break this down:

1. 2-3 years to get your issue on the political and policy agenda

2. 2-3 years to get the Commission to adopt the proposal

3. 2 years to get it adopted by the European Parliament and Council

4. 3 + years to get it implemented on the ground (or sea) or not.

You need patience if you want to change policy and laws. If you want to make sure that what you pushed is successfully implemented, you need to think in 10 years cycles.

You also need to be well resourced for 10 years.

Doing the leg work

People forget how much leg work there is in developing interest in an issue. Proposals don't jump out of no-where. I know there are lots of issues that deserve attention and many of those issues may well benefit from being addressed by new regulation or legislation. The truth is that most never are considered.

In my experience, it takes around a year to develop the case for action, and another year to generate public and then political interest to legislate.

In both cases, you are working full-out and your well resourced. This is not cheap.

Also, your organisation needs to be focused on getting your initiative adopted. The risk for any organisation is that they have too many competing issues being tabled for uptake by regulators and legislators. If you have too many, your risk slippage.

7 Key Questions to Answer

In that time, you'll find the answers for 7 simple questions.If you can't answer them and provide the evidence – real facts please – please don't waste your time.

These 7 questions are the same 7 the European Commission ask themselves:

1. What is the problem and why is it a problem?
2. Why should the EU act?
3. What should be achieved?
4. What are the various options to achieve the objectives?

5. What are their economic, social and environmental impacts and who will be affected?
6. How do the different options compare in terms of their effectiveness and efficiency (benefits and costs)?
7. How will monitoring and subsequent retrospective evaluation be organised?

I have found that most of the time people can't find strong cases to these 7 questions. If you can't, drop the issue, or delay, and find the answers and evidence.

You need to find answers to all 7 and not jut 1.

The Commission may over look one or two of them, if the political pressure to act is too high. That hurdle is high. In practice it amounts to the personal Â interest and intervention of the French President, German Chancellor, or Secretary-General .

This hurdle is not impossible to leap over – I have done it- but in practice it is best to go through more established chnnels.

Often, what you identify as a 'problem' is something to do with the local market failure or the actions of a member state. It's got little or nothing to do with the EU. If that's the case, the reason for the EU to step in and act is minimal.

Starting a Meaningful Debate

After you have 7 good answers, with preferably independent facts to support your case, you'll need to promote a public policy debate. Working with think tanks in Brussels and the national capitals is key. In Brussels, I have personally found Friends of Europe and EPC to be important for pushing ideas up the political decision-making tree. Indeed, I cling to the belief that promoting a mindful debate via well-connected think tanks at the national and Brussels level is your surest bet.

Well placed stories in the FT, the Economist, and Politico help. I found that for reasons that remain largely unclear to me, coverage in the National Geographic has an important influence.

Policy windows

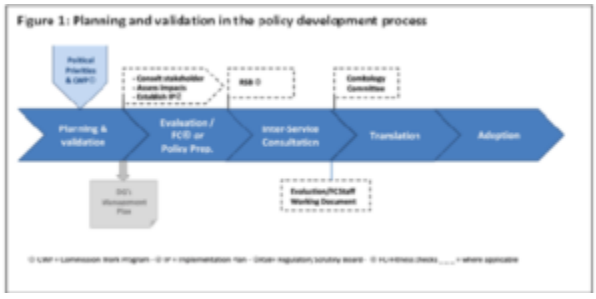
J.W. Kingdon (link) talks about policy windows to put your ideas forward. The most successful organisations have the studies and draft Bill ready in the drawer for when the political cycle returns on an interest.

Some organisations in Brussels practice this. Most don't.

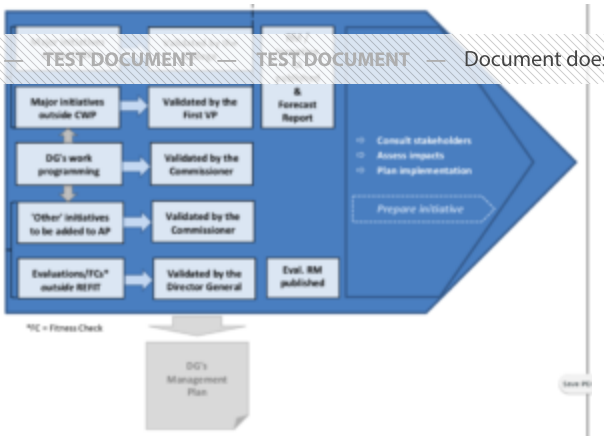
Getting your issue taken up in Brussels

The old days when you could get a good story placed in the press would lead to a Commissioner co-opting the issue and getting their staff to draft a legislative proposal have, for the most part, long gone.

Today, the windows of opportunity are prescribed by 'Better Regulation'. The Better Regulation Guidelines lay out the procedure, steps and questions that a proposal needs to go through.



You'll need to get proposal through the Commission's internal adoption procedure.



This does not man you can't use the 'policy windows', it just means you need to be aware of the Commission's time-windows for when the policy windows occur.

Work Programme

Normal Work Programme

See this note.

New Commission Work Programme

If you are looking at the next Commission (November 2019)

1. Next President's Political Priorities (July 2019)
2. Next Commission'sÂ first Work Programme (December 2019)
3. Next Commission's second Work Programme (October 2020)

The Commission Services prepare in advance a draft Work Programme for the next President for the incumbent's validation. This is being prepared.

Commissioner Confirmation Hearings

Another pathway is to have MEPs on the lead Committee(s) raise the issue during the confirmation hearings (October 2019). This may secure a political commitment to address the issue.

Fast is rarely good

In my experience, well prepared legislation is good legislation. This is not a speedy thing.

The 1st Daughter Directive on Ambient Air Pollution was drawn up by experts for 3 years before being given to the European Parliament and Council. The prior deliberations assisted the co-legislators in their deliberations. It brough the objective evidence to the table and helped clear up where the real sensitive points were.

Fast Track – Single Use Plastics

This file is an example of how fast a proposal can be taken up. This is one of the most fastly adopted – from idea, adoption, to political agreeemt – in this Commission.

Blue Planet II launched 29 October 2017 created a world-wide debate about plastics and marine pollution.

The [illegible] proposals, initially not supporting it.

Yet, this issue first surfaced in the early 1970s, and has been laying beneath the surface, since then. It did not go away, but was washed over by other related issues. For an excellent exploration, I recommend this piece by Chris Rose.

Regulating Plastics – A timescale

- 13 September 2017: State of the Union (link) and letter of intent that mentions 'concluding: a strategy on plastics working towards all plastic packaging on the EU market being recyclable by 2030″ (Draft Work Programme)
- 24 October 2017: Work programme published 24 October 2017 (link) mention "a strategy on plastics use, reuse and recycling" (non legislative, Q4 2017)
- 9 November 2017: Commission ask ECHA to start look at REACH Restriction on micro plastics
- 15 December 2017: Public consultation on Inception Impact Assessment Reducing marine litter: action on single use plastics and fishing gear (link) ending 12 January 2018
- Â 16 January 2018: Communication "A European Strategy for Plastics in a Circular Economy" (link) including:
- start the process to restrict the intentional addition of micro plastics to products via REACH
- Actions to reduce single- use plastics: analytical work, including the launch of a public consultation, to determine the scope of a legislative initiative on single use plastics
- 17 January 2018: ECHA notification (link)
- 5 March 2018: Regulatory Scrutiny Board " Negative Opinion on Reducing Marine Litter
- 6 April: Regulatory Scrutiny Board "Positive Opinion (with reservations) " Reducing Marine Litter
- 22 May 2018: College of Commissioner adopt a Proposal for a Directive of the European Parliament and of the Council on the reduction of the impact of certain plastic products on the environment(link)
- 28 May 2018: Proposal for a Directive on reduction of the impact of certain plastic products on the environment (link) (press release)
- 28 May 2018: Public Consultation on proposal until 24 July 2018 (link)
- 24 October 2018: European Parliament – Plenary – 1st Reading
- 6 November 2018: First trilogue (information negotiations between Council and EP)
- 14 December 2018: Second trilogue
- 18 December 2018: Third trilogue (final?)

So, what looks like on first glance to be 'fast' policy making, is likely something that has been in the 'policy mix' for more than 40 years. It benefited from unusual, but not unrepeatable, circumstances to get to reach the surface and be adopted.

What does good public policy look like

18th November 2018
Political Communication

I have a weakness for good public policy. Some would call it a fetish.

In Brussels finding examples of good public policy is like the search for the unicorn. It is rumoured to exist, yet few, if anyone has seen it.

For me, good public policy making moves beyond the gut response of most. Too often, the case for action is because it is 'good'. When you look behind the fig leaf of the 'evidence' put forward to advance the case, you are struck by the nothingness that it is. All too often, people out of politeness hate to say that there is a just a shrivelled jumble of evidence that does not add up.

Sadly, too often opposition to a proposal comes down to 'it will cost me money' or 'I am not the issue'. Finally, the least believed line in my 20 + years in Brussels, is 'if you introduce the proposal, I'll close my European operations'.

It's easy to spot poor policy making. Supporters and opponents resort to slogans. Evidence and expert analysis is banished to the sidelines. It is a late night bar brawl. Often ugly and impassioned , it is off-putting as it brings out the worst in people. Sober analysis is cast aside with the dregs.

Too many prefer to throw cheap threats and insults around at those who have provided sober analysis. I can only deduce they find some short-lived exhilaration. They find themselves quickly sidelined, requests for meetings politely but firmly declined, and their case discredited in the eyes of policy makers and political decision makers.

Good policy making

Instead, good public policy looks to identify if there is a problem and if there is an issue, whether EU action can help. Good public policy sets a high hurdle to initiate action. It is not something to be done lightly.

Core questions in environmental issues – my own area of personal interest – that need to be answered to understand the nature of the problem include:

- source apportionment – contributions of sources to the problem
- causal links
- can actions be taken to reduce those contributions
- costs for and against action
- what are the first and second order consequences of actions – will you simply transfer a problem or make things worse
- what the measures be proposed be implemented and enforced
- what is the reasonable worse case scenario of delivery. Over optimistic projections about how fast a law will take effect and effectively deliver are a sure recipe for disaster.

It is obvious that your case is saturated with objective evidence and data . It examines the case against action objectively.The more analytical and sober the better. Presenting data in visual form is a great plus.

In your case, you go out-of-the-way to highlight your proposal's weak points. If you don't someone is going to do that for you. You may as well draw the attention of your weak points to the Regulatory Scrutiny Board, Inter-Service Group, Inter-Service Consultation officials and cabinet leads at the start, or MEPs and Member State officials later on. It's a good thing to be clear about the weaknesses.

Good examples

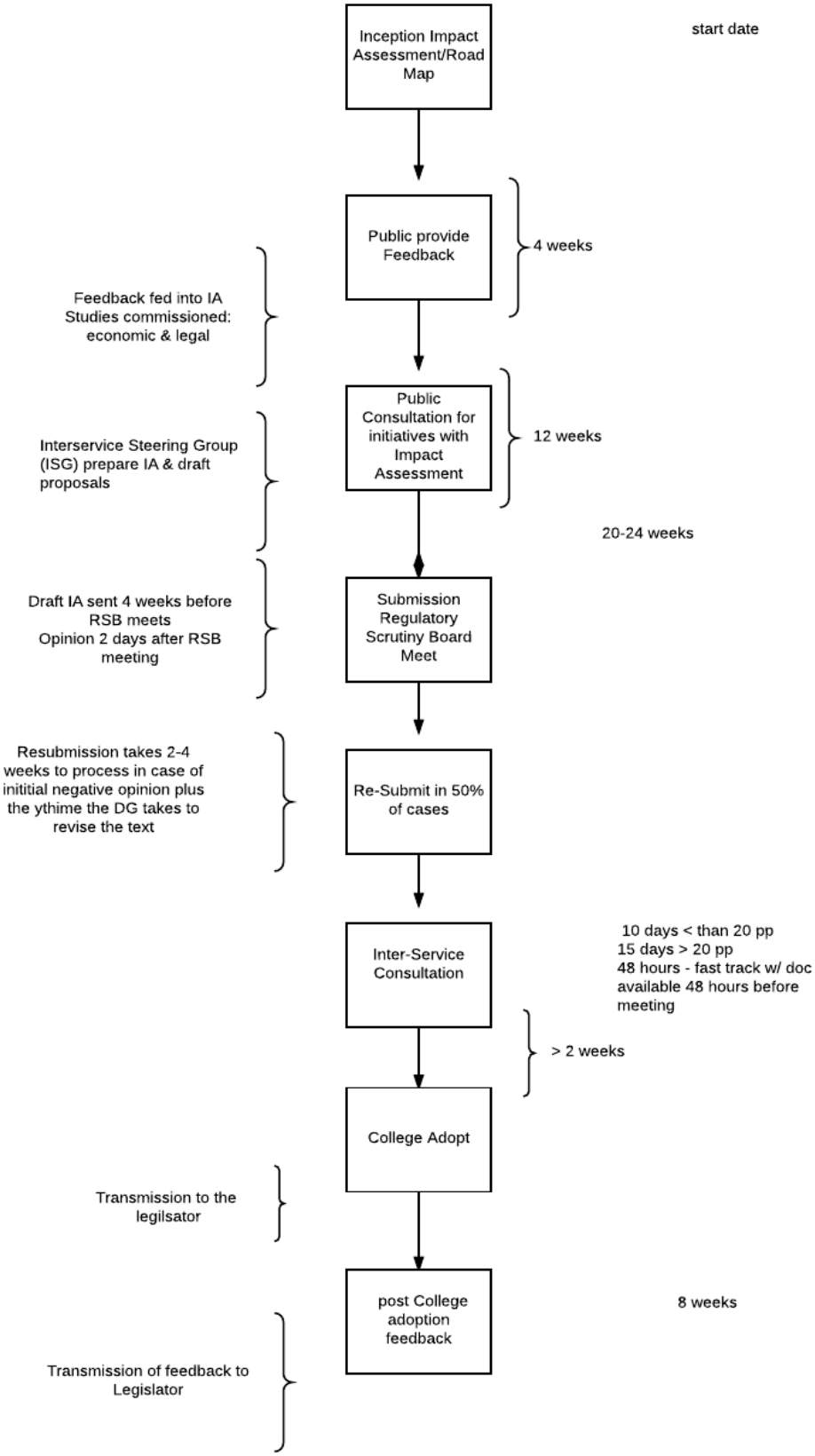
If you are tasked with writing up the basis for a directive I would emulate the clarity and thinking in these two examples:

"A Roadmap for moving to a competitive low carbon economy in 2050".

Phase down of HFCs in the EU

Better Regulation & Ordinary Legislation in one easy chart

11th May 2017
EU,Political Communication



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I wanted to put down in one easy chart how the Commission adopts ordinary legislation. This is the chart I came up with.

The advantage of the Better Regulation rules is that the process for adopting a legislative proposal is quite straightforward.

First, you have to go through the Better Regulation guidelines and toolbox. If you don't want to go through that, I have added a process chart.

Second, you need know who is involved in the Inter-service Steering Group and the Inter-Service Consultation at the Services and Cabinet level. You are going to need to know max around 50 people. That's a lot less than 200 + people you need to know when it goes to the ordinary legislation stage

Third, around a year after the political validation for the work to start, and the first road map/inception impact assessment, you are likely to see a legislative proposal being adopted.

Fourth, to be honest, the smoke signals that regulation in your area is likely to be seen many months and years before political validation. The only excuse for not seeing the signs is long term hospitalisation or political hibernation. After 25 years I have not yet encountered a piece of legislative action that "came out of the blue". As soon as the smoke signals are seen, and hopefully before, your work developing your case and story will start.

Finally, that gives you a few months to get your facts and story in a line to persuade 50 people that your solutions are the best and get them to back your side of the story.

Section 4

16th February 2023
Uncategorised

The Environment Committee's record on Chemicals

20th February 2021
Environment

The European Parliament's Environment Committee has discussed European Chemical Policy 7 times since they first met on 10 July 2019.

This Committee is going to take the lead in the revision of Europe's Chemical policy. This is due to contain 40 legislative proposals. The Environment Committee will lead on co-deciding on many of those proposals.

The clues about what interests MEPs, and what is likely to come up again and again, are hiding in plain sight. You just need to listen too what they say, and read what they write. I think it is worth while looking at the record of this Committee on the issues. Recent history has a habit of repeating itself.

The points that are raised are consistent. The MEPs who dominate the debate is now well established. The division along political lines clear. The lines that resonate and have broad political support are striking. If you want to know what points work with this Committee, take the time to watch the videos and read the transcript. It will help you adapt your language to help you win.

The agenda of the new and enlarged Environment Committee (81 members) is different from previous Committees. The Parliamentary schedule now has COVID and vaccine provision as the core issue. The challenge of finding legislative time to deal with this package of proposals is not small.

In the absence of concrete legislative proposals, the debates on the objections to secondary legislation for pesticides and REACH (link) give a proxy indication of political sentiment.

Exchanges

The Committee had dedicated discussions on chemicals at the following meetings.

1. **4 September 2019 – item 6**

Exchange of views with the Commission on the findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses (COM(2019)0264)

Minutes

2. 7 November – item 28

Presentation of the responsibilities and activities of the following agencies under ENVI's competence:- the European Chemicals Agency (ECHA)- the European Medicines Agency (EMA)- the European Food Safety Authority (EFSA)- the European Centre for Disease Prevention and Control (ECDC)- the European Environment Agency (EEA)

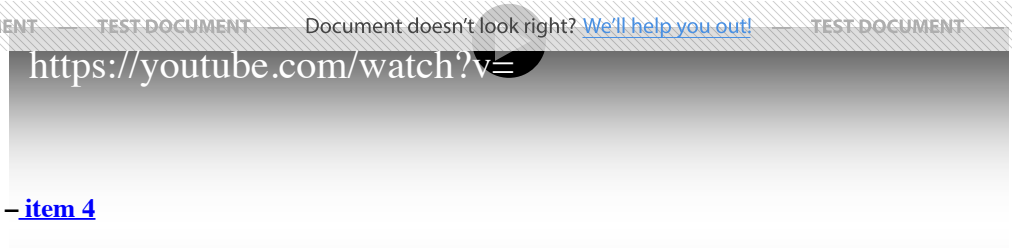
Presentation by ECHA link

Minutes

3. 2 December – item 5

Exchange of views with Bjørn Hansen, Executive Director of ECHA

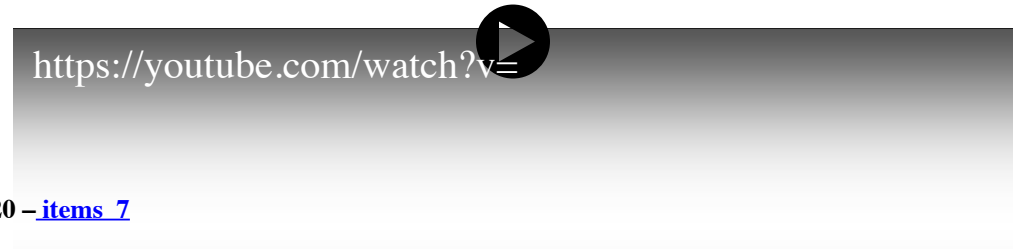
Minutes



4. 8 June 2020 – item 4

A chemicals strategy for sustainability

Minutes

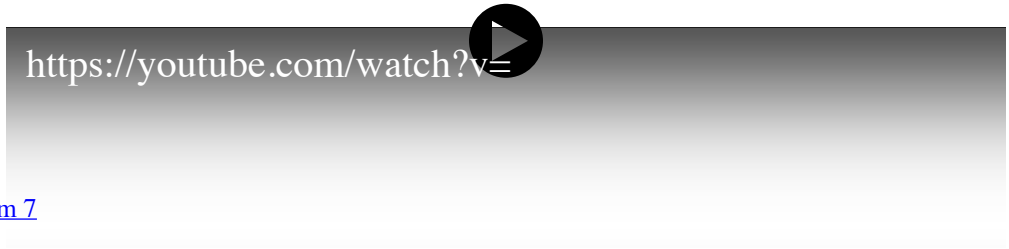


5. 25 June 2020 – items 7

Oral question for Commissioner and vote

For 79, Against 0, Abstentions 0

Minutes



6. 29 June – item 7

Vote in Committee : A chemicals strategy for sustainability

Resolution on Chemicals Stratregy 29 June 2020

Vote For 65, Against 1, Abstentions 4

Minutes

Vote in Plenary: 10 July 2020

Vote For 579, Against 18, Abstentions 84

Votewatch link

7. 15 October 2020 – item 5

Exchange of views with Mr Virginijus Sinkevičius, Commisioner for Environment, Oceans and Fisheries on the Chemicals Strategy for Sustainability

				present	absent	voters	members	
ECR	7	3	51	61	1	0	62	75.41
EPP	176	0	1	177	3	7	187	99.15
Greens/EFA	64	0	0	64	1	3	68	100
IDG	34	12	30	76	0	0	76	17.11
NI	25	2	1	28	0	1	29	83.93
REG	95	1	1	97	0	1	98	96.91
S&D	141	0	0	141	3	2	146	100
The Left	37	0	0	37	1	1	39	100

What's the future of europe's chemical regulation & measures on PFAS

16th May 2022
Environment

Today, the European Parliament's Environment Committee held an exchange of views with the Commission on their progress in developing proposals for CLP and REACH Regulation, and with ECHA on their work on the PFAS Restriction.

It was interesting to see the Commission not respond to the concerns raised by MEPs (Arena & Hazekamp) on the use of secondary legislation.

If you missed the exchange you can watch it below – the first 46 minutes.

See the Otter transcript below.

So we have a very busy voting day as well. But in parallel, we have this session. So we start with the the adoption of the agenda. I guess there is no issue we move to the changes and adjustments, nothing special beyond remote participation.
On the reporting back on trial logs, just a few words to share the fact that we started the Pops, trial log, and next trial is foreseen for May 31. And as well on those yesterday, we are heading quite well, and we have a trial log on Wednesday. That might be the final one, or the final one will be beginning of June.
Then we move to Agenda Item number four. And we will have today an exchange of views with the Commission and with a QA regarding the PFS regulation in the context of the upcoming proposals to amend rich and CLP regulations. So quite extensive and very sensitive.
We know that the chemical agenda will be very hard on the Envy table for the next semester. So we move the first with the Commission and then to a QA you have as a whole 15 minutes you are three. So please try to stick to five minutes each. And I guess we start with you. But actually,
thank you very much for president and it's a real pleasure for me to be here for the first time in the DG env committee. Following my appointment last autumn is Deputy Director General in DG environment and I'm looking forward very much to working with the committee in the months ahead. Very happy to have happy with Toyosu Christine Schreiber from Digi grow a responsible director for the Koch chemicals file, and Peter Van Zandt from eka. I will try to be brief. But my first message, of course, is that the European Green Deal and the zero pollution ambition for a toxic free environment is very much at the heart of the chemical sort of strategy for sustainability. And that we believe that this is even more the case under the common difficult circumstances with the Russian invasion of the Ukraine, as the ambition of the European Green Deal deals precisely with the existential crisis that we're facing a need, of course to be confronted head on in order to avoid do further geopolitical spillover effects and social unrest.
Moving to the key theme of the discussion today, which is the implementation of the chemical strategy for sustainability, our objective of course is to tackle the most harmful substances. And that is why we are first revising the regulation on classification, labelling and packaging of chemicals and then a bit later on the reach regulation, which come alongside ongoing discussions as well on some of the sectoral product legislation, for example, on food contact materials, cosmetics, and toys to ensure all together that the
legal framework for chemicals in the European Union ensures that the most harmful substances are phased out in consumer products and for professional uses, unless their use is proven to be essential for society. My colleague, Kristen Schreiber, will speak a little bit more about the recently adopted reach restriction roadmap and specifically the action that we are taking on PFAs. So I will just in the remaining time mentioned that on the CLP revision, we have made some good progress in recent days in our recent internal discussions on the impact assessment, which means that we are on track for presenting to the college proposals we hope after the summer break. The reach revision is more complicated. We are deeply engaged in the ongoing discussions on the impact assessment. We were hoping with this, these proposals to include in line with the strategy on sustainability at the extension of the generic generic risk approach for the most harmful classes of chemicals, in both consumer products in some professional uses, as we already had in the existing text for carcinogenic and other similar substances, but we will also then bring into the equation endocrine disruptors and the most substitutes or toxic substances in the environment. And we believe that with the generic approach, we should be
able to provide better protection and also greater clarity for industry, because these harmful substances will be based on the presumption that they will not be allowed unless their use can be demonstrated to be essential for society. The reach revision is intended to come forward with proposals from the Commission either at the end of 2022, or depending on the progress that we make in our internal discussions early in 2023. But but we are certainly determined to make progress as quickly as possible.

I just like to before finishing say a word about stakeholder outreach, and in particular, the high level roundtable that we have put together in order to support the work of the Commission in taking forward this ambitious legislative agenda. This is a high level group, bringing together representatives of industry, civil society, academia, as well as international organisations and member state representatives, in order to accompany the work that we are developing and make sure that we are best in we have the best available evidence base for the work that we're doing, but also a good understanding of how the ideas that we're developing resonate in the broader stakeholder communities. And we're very grateful for members of the high level roundtable also for the work that they are doing a sort of ambassadors for change in the outreach to the wider community. And I'm interested in particular, because we have the next meeting of the high level roundtable already this week.

We already have from the Roundtable, a very useful report on enforcement from the previous work. And a second work report will be examined at the meeting this week on research and innovation, and the principle of safe and sustainable debt by design. I would also say that it's a great place for us to draw on some of the inputs that we receive from the community. I mentioned in passing a very useful analysis of costs produced earlier in the year by the cific. group representing the chemicals industry, looking at what the potential consequences for the generic risk approach could be in the sector. Although I would say that that analysis was inevitably somewhat broad brush, since it was not able to reflect in any detail or in in a specific way, the policy options that the commission is currently analysing for the impact assessment. So all in all, Mr. President, I'm very grateful to have this opportunity with the stakeholder engagement in the high level roundtable. And the the ambitious agenda that we have. We believe that with the chemical strategy for sustainability, we're making a powerful connection collective contribution to the European Green Deal, even in the present difficult geopolitical context. I hand over now to Mrs. Shriver.

Yes, thank you. Let me follow follow up. I mean, Patrick already mentioned the major proposals we are preparing on CLP and reach on the think, according to flag on the generic approach to risk assessment as really is crucial that we significantly speed up the substitution of the most harmful chemicals, and you refer to it particularly consumer and professional products. And to do so we actually need to extend the Commission's mandate to introduce this generic restrictions and plans implementation and similar way as we had done in the restrictions roadmap, which you have seen, which was published in April.

And we also need to reform the authorization and restriction processes, because they have to become more efficient and fit for the higher ambitions which we have now with a chemical strategy. So here we need to recognise that the current level of micromanagement and rituals authorizations cannot be maintained. And we are therefore promoting broader derogations, which will apply to all companies for a particular use, rather than dealing with authorizations on an applicant, applicant basis. And let me just lay on the restriction roadmap, we have been working on the implementations of the initiatives which were identified there. And in particular, we have recently launched the inter service consultation for restriction on microplastics, which I think has been long awaited. And once we get the relevant eco opinions, we also plan to swiftly proceed with a plan road restrictions of PFAs substances, first and firefighting firms and later broader restriction, which is currently being prepared by five member states. So here, Peter Van Zandt from Mecca will let you more about the state of blank. And let me also say that in order to achieve the substitution as fast as possible, and also to make sure that this innovation actually happens in Europe, we need to give the necessary investment certainty for the concerned industry. And that's why all these plans are embedded in a so called Transition pathway towards safe and sustainable chemicals, in order to make sure that, that we have the overall holistic approach to this to this endeavour. And here again, this pathway is being elaborated in close cooperation with stakeholders, and will among others also be discussed.

The high level roundtable to which Patrick alluded, and we expect to publish this by the end of the year. And let me finally say one word on the basic regulation for AQa. Here's this plan legislation follows. It's also referred to in the chemical strategy and will require a lot of changes in actors governance and financing structures. So, in order to achieve all the objectives, we need a new eco basic regulation which will be scheduled as well for next year. And this regulation aims to actually simplify and clarify the legal framework in which eco operates and also better defines the tasks and expected outcomes, and should also optimise and rationalise the functioning of the different eco bodies. And the initiative aims to put in place I would say, a sustainable financing model to ensure flexibility and also an optimal use of the combined resources of Achor deriving from the various chapters of the commission budget. So because income, as you know, comes from fees and charges combined with an EU balancing contribution, and issues and hopefully become more stable, sufficient for the operations of the agency, and also, to the extent possible, more predictable. So let me stress once again, that through all these different endeavours, we are strongly committed to the objectives of the chemical strategy for sustainability. And personally also very much looking forward to working here with the ENV committee and the European Parliament. And I think it's a good moment now I'm see we're perfectly on time to pass the floor to my colleague, if you're not an eco, who can go more into depth in particular on the P FAS restriction, which I think is very much of interest to you. Thank you

Mr. Chair, Honourable Members, I'm happy to be here representing ACCA. Today, as long as the selection process for a new executive director is ongoing, I would like to shortly summarise our contribution to implementing the chemical strategy for sustainability. And also to inform you about the ongoing work on the restriction of PFAs. No doubt, the chemical strategy is a key element of the Green Deal, to phase out harmful chemicals to protect human health and the environment, and also to innovate towards a green chemistry. The Commissioner has formally requested eka to support on different work streams, including the impact assessment for the for reach review, the same for the impact assessment for the Classification and Labelling and packaging, regulation review, to support also on the one substance, one assessment concepts. And finally to provide support on establishing yourself standing basic regulation for ACCA. Last year, ACCA has provided its report on the functioning of reach and CLP. And this from the experience and learnings that we have found from the operation of these legislative instruments that we are advising now the Commission on how the further implementation can be improved in the future for the revision of these frameworks.

In the framework of the chemical strategy, the one substance one assessment is of course, also a concept that provides opportunities to provide more synergy towards the operation, and implementation of chemicals regulation. And [illegible] improved [illegible] we [illegible] chemicals management. And this can come from different actions, better coordination between EU authorities, also a re

attribution of the scientific work that the commission is looking into towards the agencies, and finally facilitating also the work of the agencies in the implementation towards more harmonisation. It is clear that AGIS work can be more efficient, could be more consistent, and could provide more impact if there is a further alignment of the legislative frameworks. So we

are working on our side very much to look at the different instruments and databases, how we can provide a technical support for that. But also we need more alignment on the legislation aside to be really ready to respond to this political ambition. One of the deliverables of the chemical strategy as the restrictions roadmap as was already mentioned, and ACA has provided inputs to delivering that restrictions roadmap, nonetheless, from our work on the grouping of chemicals, because looking at chemicals in groups is really a way to make sure that we can speed up risk management but that we can also avoid regrettable substitution of chemicals. And this brings me actually to the P FOSS topic, because P FOSS is indeed one of the groups of chemicals, big groups of chemicals, where this group approach is being used and the CSS has indicated that there is a need to phase out the use of P FOSS in the EU unless the US is considered essential. The problem would be for substances is that they
are very persistent in the environment. And as long as releases to the environment continue people, but also nature, animals in the environment will be exposed to increasing amounts of PFAs.
B FOSS frequently contaminate the groundwater the surface water and soils and are also found in our drinking water. And therefore, we can also find them by bio monitoring and wildlife and in humans, cleaning up pee fast contamination is very, very difficult and also very costly.
exposure to certain key facets have been also related to health problems. For example, certain pee fast are toxic for human reproduction and can harm development of foetuses several P FOSS have been found to to cause cancer, and some p FOSS are also suspected of interfering with the hormonal system. They are endocrine disruptors. That's why the European Commission and the member states have decided to take action against all p fast chemicals. And by restricting the whole class of course, we can avoid this regrettable substitution. Eka has published in February our restriction proposal for P FOSS in firefighting foams. And this proposal is now in consultation phase.
This restriction will not compromise fire safety there are alternatives available until the 23rd of September I invite all interested parties to participate and provide his input on the restriction proposal on the risks and all the socio economic aspects. And we expect that the committee's the scientific committees of ACA will provide their opinions in the beginning of next year 2023. Also we are expecting by January 2023. A proposal on the broader application of P Foss and growth restriction of P FOS from different countries that have been preparing what we call the universal P FOSS restriction. We believe that this will respond to the request from the Commission to indeed, phase out be fast and afford regrettable substitution. Thank you very much.
Thank you, thank you to the three of you. We will start now and the first round with the members. We start obviously with the EPP and Peter lizard
who is supposed to be connected
sorry, chair, there has been a misunderstanding. Normally, Maria's Iraqi should speak on behalf of the EPP but she's not yet ready. So to make it less complicated, I will say a few words, and Maria can come in to the second round.
So thank you for this presentation and the important information. I think it's a good idea to have broader derogations and not to be
so specific, because these are sometimes SMEs have to deal with the applications. And if you have a broader approach, not every company has to do the work. We have to act, the substances are persistence and can create problems for health. So in general, I think it's good. I have a question on the frame essential for society. You know, we are having a very big priority now on our feet 455 package. And I would ask mainly the commission, if they take into account their assessment that sometimes chemical substances are needed to do the transition, and if this would be covered by us that is essential for the society. Thank you.
Thank you, Peter. We moved to Maya Vienna for snd.
Thank you very much indeed.
Thank you for those presentations, listening to our different experts. Something came to mind.
If we were to use polluter pays and cost wouldn't just be seen by industry as a customer as to restriction but it costs to production.
And the presentation we heard we heard an argument saying okay, industry looks at to the cost of restriction where he would have to pay
if there were more restrictive laws.
I think we have to get companies involved more in the paying for repairs when it comes to health pollution.
I think it's very difficult for
For the public sector to really evaluate what the cost is. And the impression we have is that industry is looking at nonproduction. Whereas the public looks at the cost of repairing the damage done.
Reach and CLP is true, they have contributed to better protect our health and the environment from biochemical hazards. And we've seen various improvements, there are still improvements to be made. And the commission has committed itself to deal with some of the problems in the chemical strategy. I have various questions. Some have already been raised by experts when it came to timing,
but
pollution environmental pollution by these Pf bfas We see this increasing and becoming ever more dangerous.
The restrictions they're on and you said this at the beginning, we should be able to eliminate all non essential usages of the P FOSS
but DGN V.
We've heard from them that the PFS restrictions won't have anything to do with essential usage as a definition in it to the restrictions. So commission
question [illegible] PFS [illegible] Will yo[illegible] [illegible] in as you [illegible] ted to using

on reach and CLP?

Parallel there'll be one priority over time in CLP and another end reach don't have as much information on the form that these reviews will take? Will it be co decision?

Or will it be comitology? Lots of rumours out there has to be said. But the EP [illegible] have to play its role as CO legislator in these reviews. And then finally, the roadmap, the restriction roadmap
or we've had a recent publication, a banning concerning
elements by 2030. That's going to be a key tool.
But what about the implementation of that roadmap?
If you look at the deadlines,
and
for these group restrictions to be brought in, will that allow us to be for all of that to be implemented in the deadlines set?
Renew.
Thank you, Pascal and welcome to our guests. I'm really happy that our honourable guests mica paid us visit to Brussels. I think that we are all impatiently waiting to know who will be the next head of the agency and will help us to translate the vision for safe and sustainable chemicals into reality. Now recently, the Commission published the already mentioned roadmap for restoration of targeted substances and vice president Timmermans miss that action will be taken during the mandate of this commission. And actually, you know, even having talked to the industry, the users of chemicals are highly welcoming drama because it gives them kind of a list of chemicals to look at and start substituting Nevertheless, the roadmap itself is not a guarantee of an extension of generic approach and of a swift increase of the protection levels. What I think we need is a commitment in regards of timing for delivery of each restriction plan and an allocation of resources really, without having sufficient resources. Nikah it's not going to happen. So when it comes to the P FAS, the dossier from ex members is expected to to be submitted in January 23. Now I'm wondering if there is a possibility within a car to speed up the process in the committee's Because indeed, as I said, these are this is something where every day, we are getting more and more contaminated. And these chemicals are just building up up in the food chain. So the faster we act, the more protection we have unless cancer.
Second mode, would you improve in terms of the restriction and authorization procedures? And to the commission? Well, we have to act on on hazardous chemicals. This is obviously very clear. And I think now with this situation, yes, we need to keep on looking on the energy transition aspect on the security aspect.
But we have to keep an eye also on the safety aspect and on the circular economy. And I think it's important to have the all the criteria together because if we split them we might venture and invest companies might invest into fall substitute that will create even more problems. So I think we need to keep an eye on both. But
can you therefore guarantee that the commission and your DJs are really standing behind the level of ambition as it was expressed in the CSS and that it's translated into the reach of phone, but also specifically
On the
essential use because there's some rumours that there might be also introduction of saved views that are next together with essentially us now, is it true? Can you comment in any way of that? And what's the point of introducing the essential use when you have saved views, which could be a massive loophole? Thank you very much.
Thank you, we move to the green superpowers.
Thank you, Chair and thank you for being here to commission and a QA. Martin has already asked some of the questions which I had jotted down. So I will just move to the ones that where I am not sure whether there have been really asked, Can the commission confirm that there is no delay for a seen at the moment, at least concerning the reach revision proposal, because it's expected in December 22. But we have seen numerous delays on Green Deal legislative actions, and therefore I would be very interested to know whether this is still on the list for December. And also, Vice President Timmermans committed that action will be taking on during the Commission's mandate on the restrictions roadmap. So I wondering when we will actually say see the first mandate for restriction and I would be very grateful for having more than just a year, but rather a bit more precise. Because in the roadmap texts, it's only a years but let's take the year 2024. For maybe some of us, it would be interesting to know whether we see it in January or whether it will be under under next mandate of the parliament and also of the commission. Concerning the PFAs. I was attending part of the HBM for EU Conference, which took place a couple of weeks ago, where we had have seen that P FAS were already present in children's blood and I was wondering what kind of action is the commission planning to take in order to find out more about the current level of pollution in humans but also in the environment? There's a lot of things we still do not know we have seen several sites all over the EU where there is PFS contamination of soil and also of groundwater and surface water. Is there a special programme being planned in order to find out more about the contamination? And are they funds being attributed to the remediation of these sites, as there is a lot of drinking water of Europeans being in danger. Thank you.
Thank you before moving to the next speaker, I will formally open under catch the eye sessions or put your name on the list either in the room or electronically.
Then we move to ID there is no speaker for ID so we move to ECR we are supposed to have empirical Fiocchi. That is he's late so we move to the left and as a GM.
Thank you. Well, Pascal.
Thank you, Pascal. I'd like to thank EPA for this proposal for a PFS ban
and to deal with these hazardous materials, but it's a concern that the commission
is leaving this back door open for essential use.
We need to make sure that these hazardous substances cannot get into our bodies and into the environment. They'd have to be banned.
And we have to do that as quickly as possible.
I don't understand how these very hazy hazardous materials are still being used in all different types of products, even food packaging that has to come to an end not just in Europe but worldwide.

In the chemical strategy, [illegible] cannot be used in the EU these elements
but since

it's just we've just been talking in circles since
What about hazardous pesticides and other chemical substances? What is that what is the deadline? What are the timetable
going to be when we're going to have this PFS ban? And also when it comes to the production of these and export of them
not just inputs
CLP reach reviews there the EP has to have its full say
these essential changes which are of extreme importance. For for the Green Deal it can't this cannot be left to people deciding behind closed doors. Can you
promises commission
that this will go through the ordinary legislative procedure. Finally
commission and Ecker
I know that you know what's happening with three M in Flanders
risk responsibility for
taking for dealing with the PFS issue are in and around Antwerp.
They're just denying the fact that there is a health emergency
commission eka. What can you do just to deal with all these lies? Thank you.
Thank you. So as there is only one speaker for the catch the eye we are going to merge the two sessions. We start with some mature for the greens.
Thank you.
Thank you,
Chair, obviously all puffers
hazardous for our health. What we've seen in Antwerp, that's one of the biggest health emergencies. We've seen this century.
We were talking about a complete ban in Europe.
But that will will that be enough to deal with future scandals? I don't think so.
We need to have the burden of proof changed.
Companies will have to show
that what they're producing is safe before they can place them on the market.
And we'd also like a circularity test
because sometimes material is reused
PFAs can get into the environment that way they stay there and they would then they would fail the test. So eka can you support this this test approach Thank you
Okay, so we try to reach peak of your key for ECR. And also a message to a better reserved by SPRI key for EPP is not connected.
If you want to have one additional voice from dpps right now.
Okay, so we move now to the answers to the question. So the three of you I have to you to decide on the order.
Well, thank you. Thank you very much President and thanks to the Honourable members for the thought provoking and very constructive questions, which I think are extremely valuable in the context of this discussion. And I think that today's debate indeed shows the strong commitment of the commission to have a full and open discussion with the relevant committees and instances of the European Parliament on the important issues raised by the revision of the CLP and reach and of course, when the commission comes forward with a the the implementing legal texts to take this forward, we will be based too clearly, on our treaty prerogatives, on the issues of substance that have been raised, Mr. Luiza on the question of
how we see the concept of the central use, and this is very much at the heart of what we're seeking to achieve in the revision of region in particular combined with the
DE JANEIRO generic approach being extended to a much larger range of hazardous substances than is the case today. And the criteria that we are considering in relation to essential use are things which are either critical for society, or necessary for health and safety, and for which there is no alternative, no viable substitute. So there's the broad terms in which we are conducting this discussion. And we had a very productive workshop a few months, a few weeks ago, where over 600 participants were able to from across the spectrum of the stakeholder community to take us further into these topics.
I strongly agree with Mrs. Elena's point about the need for our work in this area, not only to look at the potential costs and consequences for the industry, recognising of course that we have a strong interest in maintaining smooth functioning of the internal market and a strong and competitor
to chemicals industry in the European Union. But it is indeed a challenge that sometimes the potential negative
impacts in terms of health and public health and the environment are more difficult to quantify, but are nevertheless a vital part of the overall assessment of the cost benefit of what we're trying to achieve. And so the emphasis that she puts on the cost of repairing the damage from the uncontrolled use of,
of hazardous chemicals is extremely well made. And maybe I wasn't clear, in my reference to the to the PFOs. Specifically, it was not that I do not see the essential use concept being a part of our future policy in this area, it's just that we do not yet have pieces within the general approach and therefore not yet subject to to this concept of essential use.
Or Mr. Hastings questions. I mean, certainly, I
am
ready to confirm that the Commission remains committed to achieving a high level of ambition in the implementation of the chemical strategy for sustainability. And the point that he makes about the need for the authorization procedures to take sort of broad context including on issues like circularity is also well made.
The issue of safe use is concept which already I think, fingers in some of our thematic and horizontal legislation, but certainly is not a pretext for diminishing the level of protection for the
for the public health and environmental consequences of the controlled use of hazardous substances for which the context of essential use is extremely important.
Mrs. [illegible] question the timescale and I
have in our mind at the moment is the is December 2022. But as she also rightly says,

Our experience is that sometimes the internal discussions and in particular, the preparation of our impact assessment, which needs to go on many inputs from consultants and others can take a little bit more time. And so I do not exclude that we push back into the beginning of 2023. But But I think that when the the the political objective remains very clearly that the Commission under the present mandate should certainly put forward proposals in good time for the council deliberation in the into institutional process. I just take the advantage also of the question that you raised on on the monitoring of the potential effects on humans of some of the, the the hazardous chemicals that we're discussing, I just happy to mention the result of a recent horizon 2020 research and innovation programme, specifically on human bio monitoring, which was published in April of this year, the HBM. For you project, which is indeed, produced a lot of very valuable data and information on chemical occurrences in humans that are Europe wide scale, and in particular, on exposure to phthalates fevers beset by phenols, flame retardants, and led, which were found in many
parts of the population, which I think clearly confirms the need to ban these substances from Con consumer goods.
So I think that's many of the questions, perhaps just
on
Mrs. Hudson camps question I understood about also the question of banning exports of substances that are banned within the European Union, that is something to which we are committed in the strategy. And we are presently considering what would be the best legal vehicle to take that forward? I think I've answered some of the questions. But the questions in particular on PFAs more specifically, and on the roadmap that I had to post and anything else, of course, thanks.
Yes, thank you. I mean, I would like to come back on the on the question for Mrs. Powers, but also others on how we are actually going to sort of implement the roadmap. Will there be delays? I think it's fair to say I can reassure you that I mean, it's a it's an ongoing it's an ongoing process. We are actually sending on a constant basis mandates to ACA, I mean, most most recently, we have one on
integration version of for PVC. We have the famous microplastics one which is close to close to it.
option one, we have one medium chain, chlorinated paraffin. So I think it's a constant process. And as as explained, we have I think what was important, but we wanted to show you that we have this roadmap, which clearly spelled out calendar, which stretches in the lead all the way until 2030. But based on, on priorities on where the most immediate need for action is that we actually have a clearer, clearer perspective on this. So I think it's important to underline, I would also like to come back on the point, which I think was quite important with federalism made on the on the point that chemicals needed for the overall transition. I think this is of course, part of the of the of the of the overall consideration when you also look at, at substitution at the wider picture of the green and
green transition from a book from a broader perspective. And that's why we also developing the transition pathway to make sure that you have this board perspective with all the different requirements, because of course, they are and rightly so, I mean, they are many challenges, to which industry needs to adapt and where industry needs to profoundly transform. And I think this is a relevant, relevant aspect which which was which was mentioned. And on just maybe on I mean, I think FIFA has also we will put in the on the on the most substantial work, I think we can hear from from from ACCA, which is to to avoid some content may be unnecessarily based on the essential youth consequent papers. I mean, at the moment. We know i mean this, this will be a
restriction under the under the current under the current process. And there, it's actually up to member states to come forward the moment to say whether they want to include the concept of consent of the central US or not, I think it's quite clear that if we're talking about papers in firefighting foams, in particular uses where you don't have any substitution, I think we will probably all come to the conclusion that if you can't extinguish electric battery, you would probably you introduce this concept here. But this is basically I mean something which will then be your suggestion when I mean this member states have started this process, what they how they want to take this is this forward. I think we all agree that I mean, as I said before, I'm very persistent, very dangerous, and that we might want me to make sure that they are limited in intimidated, not all possible applications, but maybe I'll pass the frozen to if you still have time, just for one or two pages and from echo on the actual process of the work on Pcell FIFA.
Yes, thank you very much. And also to respond to the question of how quickly can we provide the opinion to the commission, of course on this very important file? Will you recognise, of course that this is important to to make sure that the advice is at the commission and also for the scrutiny of the parliament in a way that is not only speedily but it is also very well
developed.
In the sense just to say how the process works. The proposal for firefighting foams restriction has been
published in February, we have done open to public consultation, which will take us six months, in order to speed up the work committees are already preparing for their work on the on the opinion making. But of course, after the six months consultation, we have to take into account the comments, we have to look at them. And since this is such a big group of chemicals that we are looking at, we need to do that, of course in a very good way to make sure that the advice that we give to the commission is also very solid in order to take this forward. So I think the speeding up is not so much from how quickly can we provide the opinion but it is much more of the big group of chemicals that we are looking at because we have been working on P FOSS substances over the past decades. Several of them have been restricted, but it is now that we are really catching up with this very wide restriction and really speeding up the risk management in terms of
the scientific advice essential use criteria we do not have. So how do we look at the different applications? We look indeed at whether alternatives are available, but also how quickly can these alternatives be put in place?
And actually, we have found that there are alternatives in many sectors. In some sectors, like in the petrochemical industry, where you have flammable liquids and sometimes mixtures of flammable liquids. And when you have installations under this vaso directive, that's where it is more complicated and where maybe some more time it will be needed to find the right alternatives. But that is all looked at on a scientific basis in order to provide the best possible advice of how to phase out can happen because then can happen effectively and [illegible]

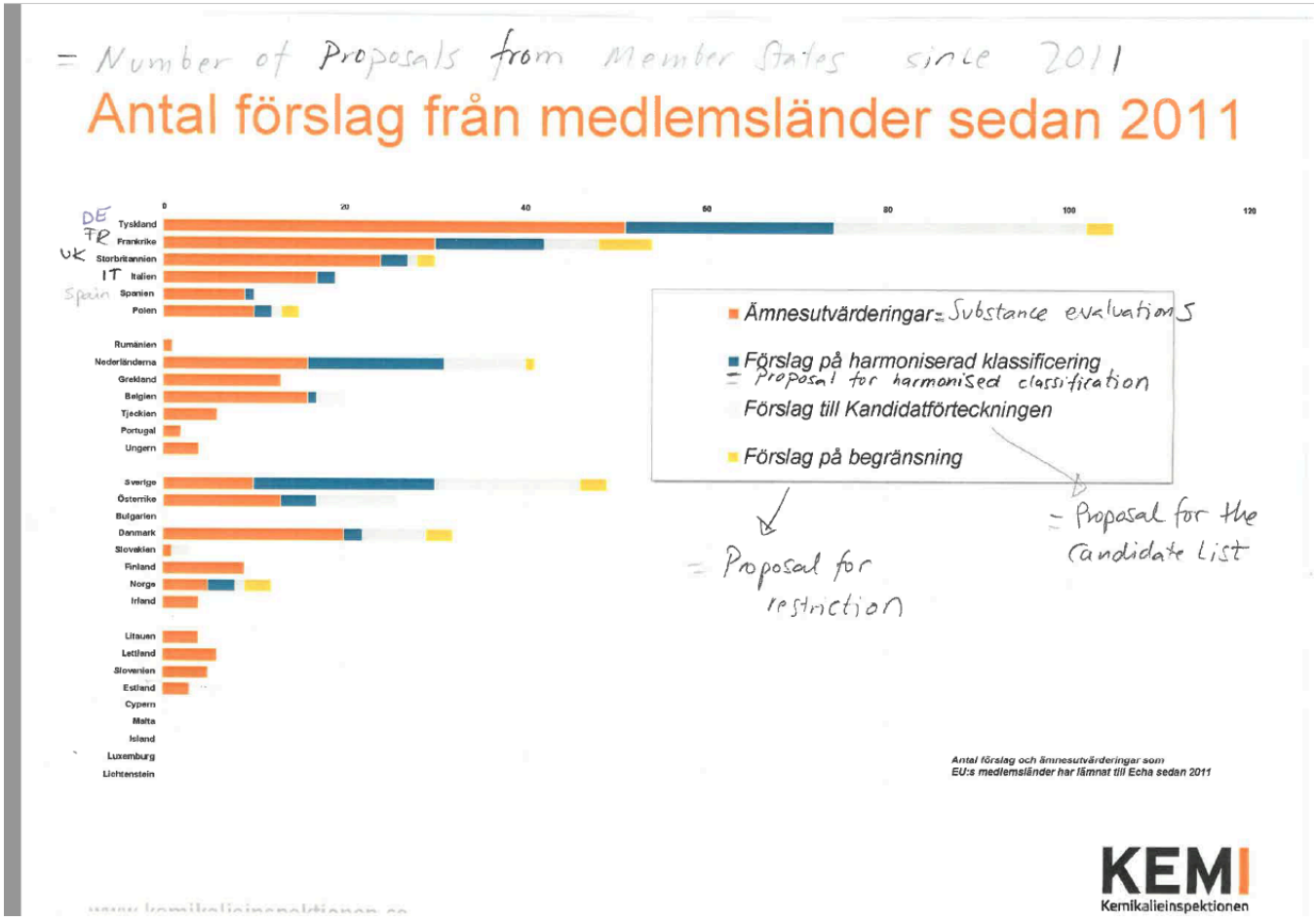
Finally, there was a question on what I consider school

To improve on restrictions authorizations, well I think some elements have been already mentioned by the colleagues from the commission when we look at authorization we have been dealing with specific exemptions very detail exemptions one by one that is taking time and resources and perhaps that could be looked at in a broader sense as was already mentioned, we also think that there is possibilities to better ride synergies between the restriction and authorization processes, so to align them better So, these are some of the ideas that we have in this in this framework. And of course, as we said we are supporting the commission to bring this forward thank you
thank you to the three of you. So we are
now at the end of this first exchange of views and of course it's the start of longer travel together.
Thank you for that and we make a very short break before moving to the next agenda agenda item for you to leave the Room.

Most active EU government on chemicals is ...

15th December 2017
Environment

Useful chart from the Swedish Chemical Agency on which countries are most active using REACH.

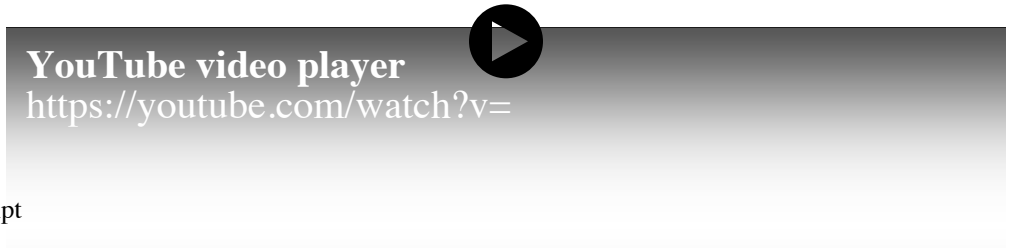


Commission updates Environment Committee on the Chemical Strategy

11th October 2021
Environment

A useful update from Kestutis Sadauskas (DG ENV) on the chemical strategy today. The Environment Committee members, who will lead on the revision of CLP and REACH, give a good sense of where the Committee sees things.

And, a final, as ever polished review from Bjorn Hansen on ECHA.



Otter ai transcript

Pascal Canfin 00:04

Are the representatives and then the guests? Yeah. So the floor is yours again.

Kestutis SADAUSKAS 00:16

Thank you. Thank you, Mr. Chairman. We are indeed, close to celebrating the first anniversary of the chemical structure persistently, we are proud of this strategy. And also happy to acknowledge that it incorporates most of the recommendations that were made by European Parliament resolution last year, July. This strategy is really a key building block for the European Green Deal because chemicals, quite literally the basis of our future, when we think of low carbon zero pollution of resource efficient technologies, we actually I think about chemicals, the chemicals, they in everything we do and contribute to our well being, but at the same time, they can cause harm. We hear some alarm bells ringing from areas from various areas. Many of our people suffer from diseases like diabetes or obesity, where endocrine disrupters could be involved. exposure to harmful chemicals is also one of the causes behind cancers, respiratory diseases, and diseases to our immune system. Persistent chemicals, like p FOSS have contaminated entire regions, and they're even found in some areas in drinking water in soils where crops grow also in crops themselves. certain sections of the population, including the most vulnerable, like children, are still exposed to harmful chemicals through consumer products in particular, that's why we need to act. And the commission remains Therefore, as committed as ever to the strategic vision of toxic free environment, where chemicals contribute to the society but also avoid harm to the planet and the current and the future generation. Let me give you a short update of where we are with implementations of 85 actions of the strategy. First of all, we're working on the revision of the two cornerstone of the chemicals digitization reach and the CLP regulation of classification, labelling and packaging of chemicals. The roadmaps for those revisions were published in May, and stakeholders gave us feedback. The two revisions will deliver on some of the main actions of the strategies such as establishing hazard classes, find the coin disruptors, introducing mixture assessment factor under each and restricting the most harmful substances in consumer products and for professional users. The Commission has also started the revision of some product legislation particular on food control materials, cosmetics and toys to achieve the objectives of this stretch, in particular to restrict the most harmful substances in those product categories. We have recently launched a number of studies to support our technical work. For each alone we have 10 studies and we are in constant dialogue with stakeholders who are consulted on the various steps, we plan to adopt those proposals next year. While we are revising legislation not to restrict the most harmful substances in consumer products, we're also prioritising those substances for restrictions within the implementation of reach regulation. For that we are working on the roadmap together with chemicals agency, which has been already discussed with member states and stakeholders and that will be published by the end of this year. Also, when talking about the most harmful substances, I would like to update you on what we're doing. As regards the highly fluorinated substances common contamination the P FOSS combination, the strategy of clients a set of actions in the sense which aim at ensuring that the use of P FOSS is phased out in you unless it's proven essential to society and the first European Commission requested the chemicals agency to prepare restriction Lucien old papers in fire fighting firms, which are the cause of many environmental contaminations.

The work for restricting, restricting all the other uses of papers has also started an initiative of some member states and the commission will prepare the legal texts for the restriction as soon as the procedure in chemicals agencies finished. More Actions on those substances I think plays on the other piece of reduction for example industrial emissions on food safety on surface and groundwater. While we are in the process of revitalization, we're also developing horizontal concepts which will be beneficial across policy areas. First, the concept of essential use, for which the commissioner will propose criteria and guidance next year. The concept will enable us to phase out the most harmful chemicals faster, while allowing the uses which are is for society, the second key concept is safe and sustainable by design chemicals materials. Again, we will propose criteria and nap options for the police application SDL. These criteria should bring clarity to what the concept means aligned policy measures and funding and attract investors. Obviously, the input of the stakeholders and our work will be absolutely essential to develop sound concepts. Safe, safe and sustainable by design brings me to another important building strategy promoting research and innovation in particular to drive the transition to safe and sustainable chemicals. The Commission has already mobilised European Union funding opportunities in particular under horizon Europe and life programmes and is working with member states to streamline the transition into the recovery and resilience national plans and cohesion programmes. A key milestone for orienting funds through a strategic approach will be the strategic research and innovation agenda for campus that we plan to publish around mid 2022. The strategy also announces one substance one assessment process to make decision making faster, as well as more consistent and predictable. This year, we already public establish a coordination mechanism which includes also new expert group with member states and EU agencies to discuss how to harmonise safety assessment across chemical digitization. We also plan to make three legal proposals one a horizontal proposal for the distribution of tasks on chemicals to EU agencies. A proposal on transparency and reuse of data to allow us national authorities to commission testing and proposal for chemical agencies found the regulation to improve predictability and stability of of these agencies financing. The one substance one assessment approach also includes the development of a common open data portal on chemicals. We plan to have this platform ready by the end of 2023. Finally, we are all aware that stroke legislation does not fulfil its objectives without effective enforcement and full compliance. In the strategy we propose actions for improving both. The rich revision should make it possible to revoke registration numbers for non compliant cases, establish an audit capacity and to strengthen the principle no data no market. enforcement is a member state competence but at the EU level we are supporting through additional measures and tools of market surveillance and to increase cooperation with online markets. This topic brings me to my final point, the high level roundtable this group was established this year and will advise the committee on enforcement at as its first topic for discussion November. The roundtable is composed of 32 members from via wide stakeholder community who not only support us in the journey with advice and insights, but they also fulfil the role of ambassadors for the chemical thresher facility. The European parliament was also invited to attend the meetings and your presence will be surely appreciated. That meeting by the way is taking place on the 25th of November. So Mr. Chair on the other members, as you will see, as you will probably see, we have been very dynamic in starting up many strands of action to achieve our ambitions. The revision of legislation making more coherent, the study's prep work to define essential lucency for sustainable visit and increased digitalization of knowledge and data and chemicals. We really count on your continued support. Thank you.

Pascal Canfin 08:45

Thank you very much. So we move to the questions with the coordinators or their representatives. And I formally open the Kgi to assess the number of questions to see if we do it in one row or two rows. So first with the EP DS occur.

Jens Gieseke 09:15

Yeah.

09:16

Yes, thank you, Chairman, dear colleagues.

09:20

In Europe, we're very proud of the fact that our industry has the world standards that have the highest order.

09:28

And there are lots of SMEs that really are at the top of the game in this and everywhere we can say that it's a very strongly

regulated market. And we tried to step up of the rigidity of the rules, being very strict and being mindful of the fact that we need to stop people from going elsewhere and stop producing for European markets. There is a threat to human health in Italy, moving away from a rational re use

10:00

Certain metals in a preventive approach cannot be the right approach, I think it is doomed to fail.

10:09

I think there's a potential danger for people in their health, doesn't that mean that actually

10:16

that potentially we may end up with chemicals being used. At the end of the day, it is the actual risk of that needs to be managed, for example, your use of ethanol for disinfecting your cell phone. But of course,

10:33

it's a matter of dosage that determines how hazardous it is. And playing a role in the risk assessment. That's a quite a serious consideration.

10:44

In the European recycling industry, we need to ensure that we effectively control and not just think just in academic or abstract terms, and of course, to having the stringent rules and will not necessarily always be the most efficient way. And scientifically, I support the commission in saying that, in Europe, we have an incredible amount of know how and expertise, particularly in our national institutes. And here, for example, in the Federal Institute for risk researcher in Germany, there's a lot of know how to be tapped into and I think that we should get them to cooperate more. Thank you.

Pascal Canfin 11:22

Thank you. We moved to Utah for a Sunday.

Jytte Guteland 11:32

Thank you, Chair. And thank you, Mr. sadowski. Thank you for joining us in the committee today talking about this important topic. As you know, we from less than the group, we have welcomed the chemical strategy and the intention to step up the work against hazardous chemicals. We support the one substance one assessment approach, and we believe that we need to do a step up on the work against endocrine disrupters, P, FOSS and other hazardous substances. We need to tackle the cocktail effect once and for all this is something really important particularly to protect vulnerable populations, not at least children who is very exposed, can you give us a little more detail on how you intend to amend reach to introduce the mixture assessment factor. I also want to express my support to the Belgian coalition who last week called for a ban on non essential p FOSS. It is unacceptable that substances pro hit that for 40 years ago can still be found in our bodies. That is quite extreme. And it shows that we are not. We are far from doing what we need to do politically here. Lastly, I want to raise the global dimension today, cop 15 starts to promote global solutions to loss of biodiversity. And in a few weeks, we also have cop 26 as we are more interlinked than ever, as the product decide is so crucial to tackle the use of hazardous chemicals. We need to go global and find Global Solutions also for chemicals. What is your view on having a Paris Agreement also for chemicals. Thank you.

Pascal Canfin 13:26

Thank you, we moved to further increase for renew

Frédérique Ries 13:31

FC bakumatsu Did I miss CRC. So this gets real messy little puzzles. For me new citizens. Thank you very much for being here. And it's absolutely crucial the commission should be here and help us by giving us the play state of play with respect to the new chemicals policies. Remember that 15 months ago, Parliament established lean lions so I would like the means taken by the Commission to take the right direction. Reach was an essential step but that was in 2005 2006. Now we need the lions for the second phase and I've got three questions we have to be brief. Three years ago eco the European chemicals agency explained something that made a lot of ruckus in the meeting lit more than 71% of chemicals manufactured had shortfalls as to their danger on dangerous 654 companies were were not respecting reach and some of the products were not in conformity and dangerous and hazardous stealth. Secondly, endocrine disruptors indeed the Commission has committed itself to establish a different second category of risks with the endocrine drop in disruptors with respect to the CLP When will you We'll be putting forth your legislative proposal to this effect. When will you commit to prohibited style substances which have been identified as endocrine disruptors in daily consumption, for example, cosmetic, certain products that are in contact with foods, when are you going to do this now, with respect to P FAS, this huge group of chemicals like carpeting, anti inflammatories, and others are many of these chemicals are being used in five member states, like Belgium, have said they're going to go further on looking into this. And you mentioned the European strategy of phasing out non essential pieces in reach. And you mentioned 2023 2024 2025. But for 40 years, we've had evidence being accumulated, could we not speed up this because it's very difficult for the European citizens to imagine that this is being put off for five years

16:07

Pascal Canfin 16:07

We moves to the greens Bas Eickhout

Bas EICKHOUT 16:12

Thank you very much, Mr. Chairman. And also thanks to the commission. Because Indeed, this this chemical strategy is very important, and maybe sometimes a bit forgotten. And when we are talking about the challenges we are having for the next decades, we are always talking about Climate Neutral economy by 2050, a fully circular economy. But the commission also said as part of the Green Deal, we will be toxic free by 2050. And for that, of course, its chemical strategy is quite crucial to achieve that. And for that reason, we also welcomed the chemical strategy, however, and this is what we were hoping to hear a bit more but but hopefully, with a couple of questions, we can get a bit more insight there. The chemical strategy was very good in announcing plans that will come some even this year and a lot next year. But that doesn't mean exactly right away that it's clear when it will take into effect. And I think this is also quite important. So it's good to have proposals, but the commission should also make clear when those proposals will have an effect on it. And maybe to start off with a couple of concrete questions. And I hope concrete answers. First of all, for 2021, you still are planning I hope the roadmap for restrictions based group approach. So the question is, of course, are you still planning to do that this year still? And then a very important question is which group restrictions Will you tackle first? I think that is very important to to get a hands on, then in the it's like near to my colleague at lunch I have we have a question on the introduction of the mixture assessment factor that is prepared for 2020 to one and how will reach be adapted for that because it's a crucial elements, but we would like to know how exactly it will play out. And the last point, we are very happy with the announcement of consumer products free from pbts. And endocrine disruptors also to be proposed in 2022. But when will consumer products effectively no longer contain chemicals that cause cancer? I think that is an answer that we would like to hear very precise as well. Not only that you will produce something next year, but also when we can have cancer free products.

Pascal Canfin 18:28

Anja HAZEKAMP 18:47

Thank you, Pascal. And thank you Mr. Santos cuz the cosmetics regulation has introduced the ban on animal testing since 2013. However, we are dismayed that the EU is still authorising extensive testing for cosmetic ingredients and the Reach for the exposure of workers and environment, even for chemical ingredients only used in cosmetics. The Guardian recently reported that 63 reads registered chemicals used only in cosmetics were subjected to 104 new animal experiments. Since in 2013, the ban was implemented. Existing safety assessment approaches without using animals could be and should be used for ensuring safety of workers and environments exposed to cosmetic ingredients. Does the commission agree that the spirit of the cosmetics regulations should be applied to both consumers and workers as well and clarify the requirements to rely solely on non animal data for the safety assessment of cosmetic ingredients in the Upcoming revisions of the two regulations. And can the commission clarify that the requirement to rely on non animal data for the safety assessment of cosmetic ingredients must be applied, and animal data rejected regardless of the location and purpose of animal tests conducted after the cut of periods described in Article 18 of the EU cosmetics regulation. Thank you.

Pascal Canfin 20:28

Thank you, I will go directly to the catch the eye list I have for the time being two speakers multinode sick and Utah Palouse, so if you want to put your name in the list, please do so in the next minutes. We start with multinode seek for renew.

Martin Hojsik 20:46

Thank you very much. And thank you, Mr. Sadaskus, for interesting presentation. Indeed, I agree with bothan, belated Happy birthday, that the chemical strategy and kind of the the toxic phenol mandate is essential, I think, without a recount where we have a circular economy, because otherwise we have a circle of toxic chemicals. Hence, I really want to dig deeper in what you said. One thing is the authorization and restriction. I wonder what's the best setup to achieve the regulation of the Moses that has chemicals and highest protection of his environment in terms of speeding up? Well, the substitution

Bas EICKHOUT 21:28

and restriction and whether there's any feedback from the consultations with stakeholders and Member States on the non essential uses? You mentioned something but if you could go a bit deeper on how do you see it firming up as well as saved by design? I think this is really important. And I may be overheard the mixture assessment factor. So what's the progress there? Under augment for restrictions? Now, will the robot allow addressing groups of substances to speed up assessment and protection? And what's the sense in the prioritisation? Or is there a sense in characterization of among chemicals? And how they will be addressed on the ADCs. And I really support also what what further Greece was saying. I just puzzled why there is need to do an impact specific Impact Assessment we know that is a problem. And I think we need to act and if you're gonna do that, how you're going to assess the savings in terms of human health and environment because we have a substantial human health costs. Also to some extent, not only about the health care, but very serious improvement of quality of life. And last but not least, on the beef us. I okay, I don't want to see light but what you're gonna do to protect public health and environment before it something comes out in 2024. Let's say thank you very much.

Pascal Canfin 22:59

Thank you and I have still two speakers for the catch the eye for the greens, starting with Jutta Paulus.

Jutta Paulus 23:11

Massey Pascoe, and thank you again, Mr. Sarah record. Sorry for, for presenting to us what the commissioner is planning to do. And I'm really glad that you have already taken up some of the demands of our green action plan for sustainable chemistry which swin give out and I put together last year or the year before, I can't remember it's so long already, where we said well, the we must change the principle from no data, no market to no proper data, no market. So I'm really glad that you are saying that the commissioner will revoke registration numbers when the data is incomplete or faulty. I would like to remind all colleagues that are still sceptical [illegible] novel entities such as chemicals are a planetary boundary where a limit value cannot be defined because of lack of knowledge. So if we have not enough law

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knowledge to assess the dangers, we should really keep the precautionary principle in mind and try to limit the contamination of the environment as much as possible. I would like to thank especially Madame Reece, poor for putting forward the problem of PFS. I get mails constantly from citizens from NGOs that are really in worries, especially in Germany we have a lot of contaminated military sites where the drinking water or surface water is contaminated with those chemicals. So I would like to know how when and how is the commission going to act on PFS not only in the registration is But also what is the commission planning to do with those contaminated sites? Will there be aid to communities and citizens that are affected? And will also the the polluter pays principle be applied even if the polluter is a military facility? Thank you.

Pascal Canfin 25:24

Thank you. And we move to the last question from Michele Rivasi.

Michèle RIVASI 25:34

Max. Thank you Pascal. And thank you commission for all that information. I would like to come back to

Frédérique Ries 25:44

over this sustainable strategy for chemicals. The Commission committed itself to providing a model to make sure that hazardous chemicals prohibited in the EU will not be produced for export. You namely said you were ready to modify write legislation, which would be pertinent by 2023. And then there was a written question from one of my colleagues, and you changed your wording, you're it's a lot more vague. And you're saying well, we could revise the regulation and prayer consentement. And with the regulation on registering an evaluation or assessment of chemicals and authorization of chemicals, could the commission clarify their wording? The why the change has been made? Can the commission is are they ready to make sure that chemicals would no longer be manufactured, or find a way to prevent the export? And then if you export chemicals, which are prohibited in Europe, that actually come back on in the consumers ditches. Now, how does the commission intend to take measures to make sure that those hazardous chemicals not are not used in production of crops imported into Europe and don't come into our food? This is very important, because how can we prohibit products that we feel are terribly hazardous, but manufacture them to export into other developing countries or countries of Latin America? Which come back to us in the food chain?

Pascal Canfin 27:29

message? Thank you for back to the commission. MrSadauskas..

Kestutis SADAUSKAS 27:38

Thank you for so many questions. I'm not sure I will be able to reply to all of them, not least because not everywhere. This. I don't have the full answer because a lot will come out from various analysis that will be conducted in the next month. But let me try to say no, we reply to the most important ones. On Mr. Guzik has questioned cooperation between authorities I fully agree and this is what we try to do it also throw one substance one assessment because we noticed that very often various authorities as well as academic institutions do extremely good analysis and very good assessments. But they're not relevant for for regulation. I mean, we cannot use them because they're done in different ways to different standards through different protocols. This is what we want to avoid wasting very good academic minds, you know, and writing very theoretical assessments, but rather to prepare assessments that we can use, or national authorities can use. So I I fully agree that we are sitting on some of the best data in the world and we have to make the best use of it and therefore data sharing can relevance I think, is one of the big objectives here. The there's been question on the on the addiction assessment, and they can say that we are analysing how to do it. Like all the other things, we'll have to follow the better regulation rules to which everybody is committed, including assessment of the impact and mixture assessment will be part of part of this, but I think we have already some some ideas. Well, first of all, we have this factors which are being used in other parts, especially in the food safety area, but more importantly, what we are considering is looking into the looking into the chemical safety assessment and to those especially that that is documented in the Chemical Safety report and the reach and that will allow us a factor of the safety for all the chemicals that registered under each. So you know this is in principle the direction in which we're going but more precise, form and shape how it will take We'll have to be seeing once we have the assessment of impacts. And once we a [illegible] would really hope that the strategic approach to international measurement of chemical the psyche will be one of those, well,

not necessarily that it would amount to that level of, of being so notorious, but at least effective. We have some international instruments and agreements in the chemicals management. But we also need an overarching approach. And by the way, the strategic approach has basically expired last year. And we have to change the way and the work is underway. And I really hope that we will be able to set ourselves very ambitious international agenda, but everybody will have to play their part because Europe is very often accused by its own internal stakeholders of moving faster and further than anybody else. And to becoming irrelevant in this, we have to drag everybody else along. Otherwise, indeed, we might risk being a bit irrelevant for any international international arena, not to say that we are going to slow down, but we need everybody to play to play their part. Frederik Aires, asked about the compliance where we are after finding soft in compliant. Dos? Yes, I can say that we are on track in together with a chemical agency whose executive director you will hear later he probably could give more testimonies to this. But we have we had an action plan between commission and chemicals agency how to reduce in compliance, which indeed was was there. And so far things are improving, the quality of the process is improving, but it's not to, to to avoid admission that is that the registrants are struggling, it's not an easy easy go because it takes a lot to give to generate all the information to make compliance. So situation is improving, but it will take still time in order to get to a fully satisfactory situation. There was question by Frederic Aires and also by Mr. Hawley sick about about the P FOSS. And you know what happens in the meantime, well, indeed, for the for this fluorinated substances, we have to follow the rules and the law to the of course doing that as far as we can. And we need to base ourselves on the best available analysis and that analysis will have to come from the chemical agency who is doing risk assessment and is also assessing the socio economic angles to that so once we have the dossier of once we have well prepared proposal a dossier analysis from the chemical agents who will be able to act bit the one that we have asked on the firefighting foam on all the other Hydra fluorinated substances that she had that which is being prepared by member states. So I really hope that these Member States several member states will prepare a good quality dose here to the chemicals agency so that we can receive this and then we can proceed with the action in the meantime the polluter pays principle applies. So member states who have the full responsibility implementing this, this this principle have to act and when they find a polluted site, they have to identify who is responsible for that in line also with environmental liability directive and the principles they're in and to hold everybody accountable if there is a proof that the damage has been done, and these actors have to also remedy or to pay to pay for that remedy. So the principles are there but of course you know that to be more precise and to prevent the whole pollution that's why we need to we need to all these associates from the from the agency which I'm pretty sure will come really in good quality. Frederick is also asked one the endocrine disruptors will be done. Well, it's been some of them they are already bent in in the in the legislation, but we don't have a horizontal and systemic approach here. So the different pieces of legislation be in cosmetics or toys or reach itself or even under the classification, labelling. The proposals will come next year, then we'll need to negotiate I mean you will need to negotiate together with the council and we hope that these negotiations will will conclude successful very soon so that we can put in place the measures to address the endochondral surplus in in various products especially in the in the consumer products. passing out about the cancer free products when they're I can say well I mean for some of the products is already banned, in principle, you know, the last restriction I think I can I can recall was the rich cancer ban in the textiles. But of course, we have to be sure that that we address carcinogenic mutagenic reproductive substances in consumer products all across. And that requires both introducing these these categories and identifying the substances under the so called chemical legislation as well as making sure that they are properly restricted or banned under the legislation which is relevant for the consumer products. So it's sort of two step approach or the parallel approach. Again, we'll talk about college inflation, so it will take some time. But I think if we send the signal to the market already now that this is the direction of where we're going, even before the laws are enacted, this will be taken up as a very serious message to the market players who probably will start phasing out these substances even before before we require, answer to Madame hadden comes approach to animals. animal testing, as in cosmetics, we have the requirement to reduce animal testing. So there is no question about it that is both a general requirement as well as under under different pieces of legislation. For example, when we implement the reach regulation, if companies want to want to do an animal testing, they have to get the permission, and only when it's absolutely indispensable, especially in life saving cases, things like for pharmaceuticals, elsewhere, this is one it is allowed. So I think we can admit that for now, we don't have fully animal free testing methods here, there yet, but but the field is really increasing and the push will definitely come and in fact, the one action, which is one substance, one assessment would help here, why is that so because what would be able to reuse the data, the non animal data, even animal data wave was used. For the other assessments like this, we avoid animal testing, which is not necessary, which is repetitive and which can be avoided some pretty sure that we are going in this direction, not guaranteed that we'll go for the animal free because we simply cannot do this, but the progress will definitely will definitely be there. To Mr. Hawley six question on the substitution. Is there any feedback from the stakeholders? I would say, well, in principle is too early to say because we are still conducting the public consultation under the CLP regulation. And we still haven't started that for the rich. So it's still early to say but I think anecdotally or randomly we can say that indeed this is happening, but to which extent, and is the speed satisfactory, I can say we need we need more evidence on this. On this. Also, he asked why you assess the impact of endocrine disrupters. If we know that the damage and how we will assess Well, we will use the better regulation rules and principles in it. In principle, the bet is made. The Commission has said it wants to remove endocrine disruptors from the from the consumer products. But of course, we need to calculate what it means and how we're going to do this. And when we do the impact assessment, we absolutely always calculate the health benefits. So it's not to say that it's easy because calculate what the health benefits will be brought about is usually very tricky. It's a lot more difficult than simply to calculate the cost to the businesses, which are very precise and a lot more easy to capture. There is a lot more modelling involved in the in the benefits, but but we will definitely do this because if we don't count all this pros and cons in the best way, then simply we don't get the full story. question to you couples and restoration in places even military on papers, and again down to the members themselves. But if the damage has been done, the remedy has to be there. So so it's again down to the member states themselves to to ensure that that this is done, but in principle it has to be done. And then the last question I would like to address is Madame reverses on export restrictions. Indeed, we are planning to act upon it, we are still [illegible] very precise [illegible] to say, but the principle is there. The resolve is there. But we need to find how best to do it. And I'm pretty sure that that

we'll be able to find that too. So with this, I hope that I've managed to answer this part of these questions.

40:00

Thank you.

Pascal Canfin 40:03

Thank you. So we will have plenty of opportunities to get back to this issues very, very soon. Regarding the upcoming initiatives, on legislative initiative you you mentioned thank you to the members. And we can move now to the next agenda item, agenda item number 11. We are running a bit early compared to the agenda, I would just to check if Mr. Hansen is with us, he is with us. So welcome to the envy committee, Mr. Hansen, for this annual exchange of views with a car. And I must say the last exchange of views with you personally, in university capacity. So I will leave martinos or chick as the contact person of account for a cow sorry, for this parliament to comment on the assessment regarding your leadership and management. But before moving to the envy contact person, meaning multinode fix, of course, the floor is yours, Mr. Hansen, for 10 to 12 minutes, to have an overview of the activity of ECHA last year, but also, maybe more importantly, to work to give us the flavour of the next month. So the floor is yours.

Bjorn Hansen 41:42

Thank you ever so much, Mr. Chairman, Mr. canfin? Honourable Members of Parliament. I hope you can hear me. Yes, perfectly. Very good. Thank you. And yes, indeed, I've decided to retire on personal reasons, family reasons, as of April 1. So this will be the last time that I have the honour to talk to you about a camp and our achievements, I do hope that I managed or you will manage to give me a couple of minutes towards the end. So I can give you a little bit of a personal reflection, because the actual important thing is for my report now, but a couple of minutes to personally reflect on my four years at the ACA, which would be great, it would be a much welcome. Thank you, then I will not include that in my in my first 12 minutes here. And basically, the last dialogue we had was in December 2019. But of course in 2020, a lot happens. And I'll be referring to that. So this is what I'll be reporting on is a bit what has happened since December 2019. I did have the honour to be able to report to you right before the summer, this year on the conclusions of our report

43:06

of

Bjorn Hansen 43:07

our assessment of five years of functioning of Regency LP, but I'll also include a little bit of that in my report here. Now since my last appearance in our dialogue, of course, a lot has happened. There's the COVID-19, the worldwide change to remote and now the worldwide remove or move back to a mixture, taking advantage of both the remote setting and the face to face setting settings to optimise to improve to create better opportunities for working. We I've also gotten the Green Deal and the chemical strategy. So there's a lot of policy debate, which is centred around the discussion of, of chemicals. And in as such, what we've been doing in Aika since 2019, and I'll come with a few details later on. But what we have been doing, I would say is consolidating the work that we've been doing, focusing primarily on our legislative tasks, increasing efficiencies, and thereby increasing our outputs and our impact. So we've also, since we last met, had quite some discussions on various topics led in PVC, the authorization process under reach, but also others. And I've had similar discussions with member states and the commission and I think there's been a continuous all this discussion has continuously helped me and the agency better understand our role in the European Framework and deliver scientific advice to, for example, you the commission and council. And I think this is also greatly improved the way we understand ourselves and thereby also how we can better serve you. Now what I'll come with is a bit of an update on the individual activities since last time, I will come with a reference to some of the learnings that we've had over the last five years. And I will raise upfront the issue of animal welfare. In my in my introductory remarks, if I go and look at the core or main piece of legislation that we are helping the institutions implement, then I start with reach. And there, I would say that reach registration, we know, the last substances got phased in in 2018. So we're now at a rather high intensity registration phase, but very continuous and rather predictable. And this basically means that all substances are now in the system. And we're continuously receiving updates and new [illegible] significantly increased the number of compliance checks we do. I reported in December to 2019, that we expected a doubling

of the amount of compliance checks we did in 219. We indeed overshot that target into 19. Last year, we were a little bit below that target. This year, we're again over the targets I would say overall in the last three years, we have more than doubled the normal output from before the discussion on compliance check. Therefore meeting the 20% target now put into legislation from 5% of all doses that need to be compliance checked. And we expect Where are we see that we're on plan to finish by 2027 the backlog of checking compliance of all those shares on the European market and registrations. So by then we will have a clear picture of how many and which substances are still of concern leading risk management at EU level which substances are of less concern. And indeed, we will have clear track of testing on substances. On restrictions. We have delivered opinions on door shares, which are broader, covering more substances more uses than ever before. So these are much more impactful restrictions. I think a good example is our microplastics restrictions proposal developed by the European chemicals agency and also where we've done a proposal and opinion to the commission. Also the tattoo inks is an example of this. And as already discussed in the previous discussion with kestutis we are working on PFS the firefighting foams will be coming in January. And in a collaboration with a number of member states to complete restriction proposal will be coming to our scientific assessment over the summer of next year. So on restrictions full speed forward and becoming more and more impactful. On authorization, I would say the main things that we have done is we have clarified better what our role is and also how we can communicate the result of our scientific assessments so that the Commission can better fulfil its role and you Parliament can better scrutinise this we've implemented in all the work that we're doing under authorization and thereby also continuing and full speed, delivering opinions in that area on classification and labelling and occupational exposure limit values. This is more or less routine, higher intensity work, but we are getting more and more requests for more high impact substances. For example, the development of an occupational exposure limit value for asbestos, bio science, I think, I think there was mentioned in the previous discussion about that as well have shown their importance in this pandemic in particular and in relationship to disinfectants. So it's important to is very clear we in eka have increased our support to member states for them to fulfil their obligations because obviously there is a resource issue in member states to fulfil there's this is paying off there is an acceleration, but we're not too optimistic that the programme will finish on time as the sat down in the legislation, because of lack of resources in Member States. We look at some of the additional tasks we've been getting that we label environment tasks, but these are mainly because they come from our Sheffield imdg environment, then we have delivered on the database in the waste Framework Directive on substances in articles which was required, we are delivering on the drinking water directive helping the commission implement. And there we did get the resources we needed to do the work for which we're very grateful. And also on the AIDS environment action programme, we are anticipating to get resources and have already started the work and to develop chemical indicators based on existing information and existing it infrastructures that we have. So that's a bit of a report in terms of the work that we've done. Up until now, if I look at the learnings that we have, overall, looking back in the implementation of the legislation, then looking at reach, we definitely see that substance evaluation, which is one of the evaluation legs being done in reach is not meeting its objective. Whereas compliance check with some tweaks, for example, enabling the registration number to be withdrawn as kestutis mentioned, which would enable that process to be both efficient and consistent. In the restrictions area, we see overall, it's working very well, but can of course be improved by looking at broader and even more impactful restrictions. On authorization, we definitely believe that it subsystem is working towards the objectives of authorization, but it is not very efficient, and therefore, some approach looking at the strengths of both restrictions and authorization, but also other legislation, which probably be more efficient and consistent. Overall, we observed that resources are limited in member states and authorities. So member states and authorities are having trouble meeting their obligations under the current legislation. And this is hampering on the delivery of reach CLP. But here also I'll throw in biocides compliance of industry is an issue not only in terms of the data that we inika test compliance on, but overall. And this is therefore not only reach evaluation issue, it's an overall issue. And we do think that therefore this needs to be reflected upon on how to overcome or how to better target either compliance or getting industry to be compliant. And finally, we've also learned that the inter linkages between reach and CLP and other legislation, I've definitely not delivering the efficiencies and consistency that we had all hoped for Originally, we see that there is very little, if any significant interaction and usage of the work on reach under other legislation. Like some of the learnings, we definitely see overall, that's reach as an instrument is getting getting there towards the objective set, both in terms of human health and environment, internal market competitiveness, and on promoting non animal methods. But we are slower than expected, and we're having less efficiency and less consistency than expected.

53:51

So

Bjorn Hansen 53:55

that's I think, we'll conclude my report on what we've learned if I turn to the animal animal welfare issue, then I think we've made progress in the agency in terms of looking more and more at only funnelling those substances for which we expect risk management to be needed to be subject to compliance check. And thereby for generating the data. We are implementing with about 100 people in the agency the requirement to test at with to test only as a last resort. And we're also doing a few things which actually go beyond our mandate in order to promote animal welfare issues, and in particular in the area of sharing data and predicting data. So in sharing the data were a driver in promoting international worldwide format for sharing data and we also [illegible] and developed the OECD [illegible] process to [illegible] all authorities around the globe. Now, if I look a bit forward, I think on the animal welfare issue, it is worth noting that it's a

total win win win win situation for all parties involved, if we would be able to move away from animal tests, it would mean that we will be able to get results about the undesirable effects of chemicals much faster. That's great for industry because they can test their chemicals in much, much earlier in their marketing phase into there by screen them themselves from marketing substances that shouldn't be marketed. Rather than the current system, where effectively we wait until 1000 tonnes before the profits are so high that the tests can be paid for that actually demonstrate that the substance shouldn't have been marketed to start out with. So that's one exemplification of the fact that such testing would be advantageous also for competitiveness, also for the internal market also for innovation. So I think there are many other arguments on top of also the very valid ethical arguments of not using animals for such purposes, that basically say, we all have the same objective. The main issue here is that the current system for risk managing chemicals worldwide is based on animal studies. Look at the wh o definition for endocrine disrupters, it's about seeing effects in a full animal. And therefore, in changing the system, the whole system needs to be changed. And that decision, and also the assessment to do so is a policy decision, which of course we are is a policy assessment and decision, which we of course, would be very, very happy to contribute to with our knowledge and insights. So I think with that, Mr. Chairman, I'll stop my introduction in terms of what we've achieved, what our learnings are, and then the specific point on animal welfare. Thank you.

Pascal Canfin 57:31

Thank you very much. So we move now to the envy contacts person for your agency, meaning multinode fsic. floor is yours for a couple of minutes.

Martin Hojsik 57:43

Thank you very much, Pascal, then, Mr. Hanson, there'll be on now first of all, let me really thank you for all the work that you have done for improving chemical policies in the EU and I really had was an honour for me to work with you over the last bit more than two years, even though the physical meetings were very, very limited. Now, he will also said to me that we did not make it as an entry for for a visit to occur before we leave the office, I hope it will make it later in the year to meet with a new director, who will have really big, big task to kind of step in your shoes. So leave them behind, although there it's something which I'm hoping that the new director will have a similar mission like you have, and that is making the Europeans protected, the European environment protected and at the same time supporting the competitiveness of the chemical industry. But let me get also to some of the points that you raised. And I then have a couple of questions for you

Bas EICKHOUT 58:53

to not only because of the karma writing your departure kind of thanking you, but sorry, but also really looking into the challenges ahead. Now the commission mentioned several options for the future of authorization and restriction. I wonder what articulation of authorization and restriction you think would work the best to really achieve the regulation of the most hazardous groups of substances that are produced and used today. And what is at stake if we delete the authorization. Now, we know that there is despite the rage being rolled out, there is still data missing regarding many chemicals on the market, that we are exposed to, which leads to the problems such as skoltech cocktail effects and emerging threats from unknown substances. Now, reach aimed at is aimed at creating information registration to ease an increase the restrictions of hazardous chemicals. Now, it nevertheless takes us still too long to answer and before we make a transition from data

1:00:00

To regulation,

Bas EICKHOUT 1:00:02

what are in your view the key things to improve to achieve a quick phase out of hazardous chemicals? And should we be requesting data for low tonnage chemicals and polymers, or anything else? And how do you think we should be better with data?

On the non compliance and you touch it in your speech? I'm wondering, really,

Bas EICKHOUT 1:00:26

what is the discussion with the commission regarding the possibility to revoke registration number for non compliance registered? And

Martin Hojsik 1:00:35

what about the request for mandatory and regular updates on registrations? There's

Bas EICKHOUT 1:00:41

now also many really complex and overdue restrictions that will be soon proposed the member states for example, on p FAS and bisphenols. Now, how will Aker support the member states through the whole process? And do you think that we should be more strict regarding delegations? What do you think is the biggest obstacle to achieving zero pollution, ambition and truly circular economy? Because we talked about in previous presentation also is for me, kind of the chemical strategies importance that but we have to look at chemicals as a really important part of the puzzle in terms of circular economy, climate, biodiversity and human health protection. So what are the issues? According to that we are overlooking and will be keen on visionary statement and where do you see the role of the cautionary principle the whole thing? Are we actually using it?

1:01:34

And last but not least,

Bas EICKHOUT 1:01:37

and I've been always talking about I think every single meeting and also in the budget committee and a budget discussions money. Now, how do you think is Aika suited in terms of the financial stability and the financial forecast? Should I keep on pushing the commission for more money for Okay, thank you.

Pascal Canfin 1:02:01

Thank you very much. So we move to the catch the eye and I have for the time being for speakers myos pyaar, Ki for the VP uj, Paris for the greens by say quit for the greens and another GM for the left. So if you want to put your name on the list, please do so in the coming minutes. So we start with my SPRI key for APB.

Maria Spyraki 1:02:36

Thank you, Pascal. Thank you, sir. Thank you very much for giving me the floor. There. Mr. Hansen, it was an honour and a pleasure to work with you during the last few years, especially when it focused on the chemical strategy of sustainability, which I was one of the authors on behalf of VPP. I would like to table a two questions regarding the performance effect that you've already mentioned, when it comes to rates, where and how do you see that all effects? Under the new EU chemical strategy for sustainability? And how much prepared is the agency for taking over any potential new tasks in terms of resources and capacity? It's about the funding. And if you do foresee any need for structural changes within the agency in order to meet the new needs? And if so, will they affect the delivering of the current task needed first of all to reach and of course, to ba si tu CLP regulations? And my second question is of these few of them have tested which one of these said that it is very, very sensitive. And I would like to ask for your opinion. If Finally, a is right or not easy reality or not. But based in in recent assessment, there are a lot of scenarios that the there's likely to be an increase in testing of numbers from animals as a result of the comment was made in the IMP in the chemical strategy for sustainability. So when the number finally be

increased, and if it is, how much Thank you very much.

Pascal Canfin 1:04:26

Thank you, we move to the greens Bas Eickout

Bas EICKHOUT 1:04:33

Thank you very much, Mr. Chairman Pascal. And first of all, I also would really like to thank Mr. Hanson beer and if I could say I think for the exchange of views we had on on many of the issues around your agency and chemicals and the role of chemicals in our future society indeed. I always very much appreciated how you did that. So from my point of view, it's really sad to hear that you are

1:04:58

quitting your job and

Bas EICKHOUT 1:05:00

I understand the reasons but still it's it's a it's a pity. So I very much appreciated that and I really would like to stress that. So probably then also having done that, then maybe we can also achieve would like to ask a question more on a you know, stepping back a bit looking at how the authorizations are going at the EU level. I think what what what you are seeing developing is probably something that makes you a bit sad about it is the kind of the, the legalisation and more and more court cases that are around some of the authorizations were quite often we as a parliament were forced to take that step against a commission, because we felt that the Commission was not dealing properly with reach. And quite often until now, the court also said that we will write in that judgement, let's see how there's still some ongoing court cases, as you're very well aware, I think you are also very well aware that of course, every time a car was used as an arguments, law, they have done a rock opinion, and we follow and, and if you then go into the rock opinion, for example, quite often, you gave all the arguments, but it was sometimes quite hidden in it. So also giving the opportunity for politicisation of xR basically using Akka in either way. So it would be very much interested to hear from you how you see that development and how you think Akka can do better in in not being used politically, basically. And for example, I could imagine that you just refuse any opinion, if there are no proper data. So there is an authorization request. And you say, Well, now we can all write what we know. And then maybe somewhere, make the point very clearly that there was insufficient data to give a final conclusion. But if you don't write that very clear, then it will be used anyhow, your opinion. So probably sometimes, it's just also better to say, we're not doing we're not issuing an opinion as long as the data are not there. And and I would just be wondering how you see that development and how, you know, could change its role in these authorization fights that probably we will see more often still. And for the rest, it was really a pleasure to work with you. Thank you very much.

Pascal Canfin 1:07:14

Thank you, we moved to Utah police. See for the greens.

Jutta Paulus 1:07:24

Thank you, Chair. And thank you, Mr. Hanson, I really would like to echo my colleagues here that it is a true pity that you're leaving, as you're so dedicated to the chemicals issue and your successor will have really big shoes to fill. I don't know your your number, but you probably know what I'm talking about. And that has really been a pleasure working with you. As to the future developments. I think there is one loser when it comes to animal testing, becoming less important. That is of course the breeding facilities, but I'm not very sorry for them. But that leads to my next question, how do you assess the possibility of translating the diet data which was developed using animal testing to a new approach, because Up to now, non animal tests have to be adopted to fitting the results of animal testing for example, when it came to eye irritation or skin irritation, whether humans can model test was adopted adapted to deliver worse results actually asked to be comparable to the rapid tests formally used. So what role do you see to be done this side I don't [illegible] like to know what you your assessment on the benign by design approach. So to say that you do not put chemicals to registration or the market if they are

not benign by design in the first place, thus saving a lot of rabbit D work afterwards. And let me let me end with just telling you again, that we will miss you terribly. Thanks.

Pascal Canfin 1:09:18

Thank you, I'm sorry, I don't have any gift for you.

1:09:22

But when when you come in person to Brussels also we'd be happy to organise something

Pascal Canfin 1:09:29

when relevant. So we're now we move to the left and an ASIC.

Anja HAZEKAMP 1:09:37

Thank you, Pascal. There. Mr. Hanson, thank you for your presentation and also for your work. And before you leave a QA I have many questions for you. In your presentation, you mentioned animal welfare several times and how we need a system change to completely phase out animal testing. Could you please elaborates on how to achieve such a system change in your opinion. And I'm very glad that you focus on animal welfare in your presentation. Can you explain what what is changed? Because just a few months ago 18th of May you work spoke at a European innovators forum and then you stated that we currently need are 14 years away from being able to effectively predict toxicity of chemicals without the use of animals. However, we didn't see any evidence to support your statement then and we would expect the director of Akka to put maximum efforts to implement Article One of reach to the promotion of alternative methods considering this aspect of reach mandate is currently left behind in your role of executive director of an EU agency. Don't you think that you are not only misrepresenting the current state of safety science, but also undermining ongoing research efforts in investments at EU level that are prerequisites for innovation and better site safety. EFSA, aima, the United States EPA and FDA all have puts in place roadmaps to proactively reduce and replace animal testing and integrate non animal methods. Yet, ACA actions remain limited to just three points. When we look at the 2021 2024 workplan. Given the parliaments disappointment, Acas limited ambition in this regard, which we registered in our report on the ACA discharge, can you explain why this still does not appear to be a priority for acca? And will you now be working on a similar roadmap? And then my last question, the European Medicines Agency in its regulatory science strategy to 2025 says that non animal methods including organoids organs on a chip computer models can be more predictive than tests on animals and therefore better at protecting animal health, people health and the environment. Ms innovation Task Force has been charged with the responsibility of advising medicines developers free of charge on the best way to use non animal methods. Do you agree with a man that what? and What plans do you have for similar work within ACA? Thank you.

Pascal Canfin 1:13:06

So we don't have any other members for the catch the eye before going back to you beyond we have the Yeah, we give the floor to the pier representative on the care management board for comments. And I'll when Martin was with us remotely.

1:13:37

Smoking this person was big button. Thank you.

1:13:56

Martin, please press on this big button. So you have the line is blue on the bottom of your page. It needs to turn red for you to be able to be heard and seen.

Pascal Canfin 1:14:23

Okay, unfortunately, it doesn't seem to be working. So back to you beyond and, of course, that's the time for your personal remarks as well.

1:14:48

Mr. Hanson is pressed on this big button. Thank you.

Bjorn Hansen 1:14:55

Thank you very, very much and the best present I think that anybody could give me from the European Parliament is what you've already given me in terms of the words that you have expressed. So I thank you dearly for that. And I'll carry that with me in my early retirement with with with great, dear love and care. To your questions, I'll I see one package of questions around animal welfare, testing abilities, but also innovation and that fits a little bit all together. It's linked also to use the policies. Question I believe it was on on design, benign by design. So I'll do that in the end. That's more forward looking. And then I'll just go through the questions as they were. Martin, first of all, many thanks to I've enjoyed deeply working with you and your enthusiasm and your your vision. And I've learned a lot from that. restrictions and authorization. And the way we see it is that both restrictions and authorization have their impact on industry and on their behaviour. And the way they do that are different. So that means that if you delete one or the other, you will remove one instrument that you have in acting on industry, in particular authorization we see is a very powerful tool to push substitution in a lot of settings, and therefore by removing it, you wouldn't have that tool at your disposal. The way we see the world there, I would almost throw all chemicals legislation in it and look at it in terms of one substance, one assessment, in effect, the substance and the harm it does somewhere. It doesn't matter which legislative framework or instrument you are using. Neither the substance nor the the human or environment that's being harmed care, what they care about is that that harm ceases. And therefore, the right way to look at it from our efficiency consistency perspective is to find the most efficient instrument to address this specific concern, and not divide up the ledger, the substances between the legislation. So basically, you should find the legislative instrument or instruments and processes, which best in the most efficient, and the most consistent way can address the concern. And that's why we believe they're looking at Rick reach restrictions and reach authorization more as to ways of addressing problems. And therefore for any given substance, you might want to use one for some uses another for other uses. In terms of the data Miss missing. Basically, we believe that by 2027, we will be there in having identified which data is missing and needs to be generated compared to which data is there and shows that either a substance is a problem or not a problem or where industry has maybe not done as good a job as they should have. But we really don't believe that the substances of concern anyway. So we will have a much clearer picture in 2027, when we finished the compliance action plan. As to what are the problems and there we already now have quite some idea about the scope of the problems that we will face in the future that we will have by then when we know so much more. What is needed to quickly phase out chemicals of concern, but I think that and I'll get to that later on. It's linked to the animals and the benign by design. It's you need information early on rather than late to be able to figure out if a chemical is of concern. And you need to do that before investments are made but later Later More about that later. In terms of non compliance Yes, we believe that it would be very efficient if we could get if we could withdraw the registration number when there's non compliance. Basically, what we see is that the longer the chain of events is involving more people between what we observe in occur and the action taken, the less effective action is and therefore If we find a problem with an only representative who is situated in one member state who is actually representing an importer in a different member state, and we see a problem, that interaction and getting things coordinated takes a very long time and very often becomes ineffective in terms of enforcement. So we believe that's a definite way of getting there. In terms of regularity and mandatory updates. The main thing that we think this could bring us is stable fee income. We don't believe particularly that just mandating people to update their registration or shades that they necessarily will become more compliant with that mandate. But it is good for our stability and fee income. P fast, I think I mentioned that, that will be coming out for the fire fire firefighting foams in January, and we will with Member States by summer next year. Basically, we are helping the member states, we're actually developing the registration dossier with what we call substance identity and grouping. So basically identifying what is the substance actually, and what groups or subgroups of pee fast can you find, in order then, to carry that grouping approach through in the restriction recall, there are several 1000 of these substances. So there is quite some inventory work to be done. And that's what we're doing. Circuit secularity zero pollution ambition and looking forward. Well, I think the realisation which is in embedded in the Green Deal, that the materials we have today are not circular. And all materials are a mixture of chemicals. So if the material is not circular, it's either because the material is wrong with the chemicals in and or we don't have the right chemicals making the materials. And it's probably more than that we don't have the right chemicals to make circular materials. So there's an enormous amount of innovation that's needed to get us away from the chemicals that produce materials that are not circular today, we also have the challenge of energy consumption that industry chemicals industry, it doesn't help only if, if the supply is green, also the consumption needs to be reduced. And that all is driving new chemistry and the need for new chemicals that is [illegible] the circularity of [illegible] to the [illegible]

I'll come with with within the end. And then we actually can have a system where you can design chemicals to be circular, or

at least avoid them being unsafe, if they're designed to be circular. To your eye, we're using the precautionary principle enough. I mean, that's for you to judge. I think from my site and the work that we do, we very systematically include assessments of uncertainties in the work that we do. And we vary systematically, when you have a substance which is problematic. approach it by telling industry that we will have to we recommend the commission to restrict that use unless you show us differently. I think the microplastics is a good example of that, where basically we concluded microplastic presence in the environment is not a good idea. Therefore any use needs to be restricted that make leads to emissions. And the whole story was about which uses should be restricted when in order to enable substitution and not market disruption. So I do believe that we've managed to implement it systematically. But it's of course for you, our part of it but it's for you to as Parliament commission council to decide whether we've done this good enough. And we've actually enabled you to take the risk management decisions, the precautionary decisions that that you need to take the if I look at Maria's and thank you also Maria, it's been also a great pleasure working with you and brainstorming with you and also understanding your great ideas and how we can help support implementing them. In terms of the role of account, and competence and resources, first awkward resources. I believe that we have managed in the agency to consolidate our efforts in such a way that we can deliver what is expected of us at the moment. So I don't play for more resources to do the work that we're doing today. But I do plea that we don't get given tasks without there being an analysis of new resources that come to us Should we get new tasks nor that If you want us to do more within the current stance that we're doing, then we also need more resources. In terms of competence for the future, I'm confident in it because strategy, HR strategy and the way that we look at our people as a resource in the agency, that the competencies we have will be continuously developed to be the competencies that are needed in the future. So I'm very confident that we can continue being a competent Centre for chemicals management, also looking at the changes that will be coming with the chemical strategy. And with time they're sorry, then to bus. The issue of legalisation and politicisation of arguments, I think there are two separate the legalisation simply shows that the work that's being done matters. And the courts, I find are tedious and workload, but they provide clarity, where there are differences of view. And therefore the fact that we go to court, the fact that you disagreed with the commission, and we took the commission to court where we played a role was helpful to find out what is really the way that reach should be implemented. So I believe deeply in our legal system as being the way of creating clarity when there are entities or or people who disagree, and that way find a solution. And I believe that it's working that way and showing us to do that. The politicisation, I believe that we in eka have learned a lot over the last years, that it is actually our responsibility to communicate to you in Parliament to the commission and to Council and also to member states in a way that you understand. And I think that we've not been able to we've not done that good enough in the past. And we are definitely improving. So we've been communicating what we think, what we think, but not necessarily in a way that what we think comes across clearly. And I believe that the what, what what we've done on authorization has improved that communication. And we're definitely learning from this. And we're trying to improve in all areas to better explain what we're doing and thereby not be used politicised in the way that that you were mentioning Boston. Yes, indeed, I agree that this is I've observed this happening. But I think it's our role to explain better for this misuse to be be reduced, and also to ubass. Many, many thanks for the kind words. Finally, before turning to animals and innovation, basically, if we can have an opinion that says, no opinion, because we don't have data, yes, that option is always there. Up until now, we've not had to use it. But there have been cases where we understood our role and what we needed to deliver in one way, and you in a different way. And the court has now helped us figure out how that is. So maybe this is this situation may occur more frequently in the in the future, because the court has told us some technicalities in terms of how to do authorization where we, in the past didn't get enough information, and still have an opinion. And now we need more information to produce an opinion. If I tried to do the system change and animal welfare and how we implement how we see forwards. Then back to my introductory statement, the perfect world would be one where a company in its research laboratory manages to make one gramme of a chemical. And that would be enough to send into huge high throughput screening of in vitro and partially and computer based calculations, which would then say this chemical is sustainable, is safe and sustainable or is benign by design or not. And I think that is definitely the vision and the the landing point where we all want to get to, but there are quite a lot of steps to get there. And just to say, I never said it will take 40 years. I said it will take decades if the efforts would continue as they are being done now. And yeah, if they're being done the way they're doing now, and if the legislation doesn't change, meaning that we see They'll need to use animal studies to identify endocrine disrupters. And of course, a lot of things can change we can, it can become a political priority, it can accelerate. Now, for me, as I mentioned in the intro, there are basically two systems either we rely on animals, and then we work as hard as we can to make one by one replacements. And with that, and I believe there's a lot of room for improvement to speed up that assessment. And my decades basically came from the fact that I've been working now 31 years in the areas of chemicals management, and I've seen in these 31 years, what tests have been animal tests have actually been replaced. comparing that to the challenge of replacing the extended one generation reproductive toxicity study, which is designed to identify endocrine disruptors, and they're looking at the last 31 years, I do believe that we definitely won't manage within the next 10 years to replace fully that study. So how do we get there is basically to have an open discussion on what are the the advantages of the various test systems, and then basically feed into a policy decision on whether it's time to change to a non animal or when is the time right, and if that should be done to change from an animal system to a non animal system. Again, it of course, has repercussions, because the uncertainties in the current system, we understand, and there are definitely uncertainties and imperfections in the current system. But there's not a unit an equal understanding of the uncertainties on the other non animal methods. And we need to have a proper discussion, in order for policy to take the decision if and when to switch. And if not switching how best to accelerate the progress towards non animal methods. One to One replacement. Again, it's a policy decision. But it's one where there's a huge advantage for everybody if we would be able to get them in terms of a roadmap or a strategy. My reflection on it is that we have one obligation and one clear obligation, and that is to ensure testing is done on animals as a last resort, the whole organisation works on that we're all geared up, and it's completely delivering on that. We don't have a mandate to be to develop alternative methods, that is not part of a cause mandate. It's, there are other entities who have that mandate. But even though we don't have a mandate, we still actively work on the data bit, which basically is all about [illegible] place can be used everywhere else in the world. And we're also very active in developing a toolbox, which enables the best application possible of non animal

methods. I think just some indicators of how active we are. The acronym na n num was invented in eka that there's another trilateral project called opherack. Working with the US and the Canadians on this, this was across initiative to do this work, we started it. So it's not that we don't work on this. We it's just these are not main core legislative tasks that we have. And

therefore we're not reporting maybe as as well to you as we should have about all the activities that we're doing. I think that more or less concludes the statements that answering the questions. My two minutes are simply to say that I feel enormously privileged in my whole career, I've worked 31 years for the European institutions in the commission and an acre to have been allowed to fill the positions, at least temporarily, to be you know, the custodian of various positions, and be allowed to be part of this absolutely amazing and wonderful democratic system that we have in Europe, which includes you interrogating me, but it also includes me trying to explain to you what, for example, in this case, it guy thinks, I think it's absolutely amazing that our system works so well as it does and it's very much thanks to the individual people who feel like I hopefully managed to do the posts that I've been able to do. And it's this fantastic collaboration, energy and will to achieve a solution together. Which is is fascinating and is driving the union. And I must say, I've every day I've had the pleasure to work with parliament, I come home, I tell my wife how absolutely amazing our democracy is and how fantastic it is to work be part of that machinery. So without final words, just to say I'm extremely grateful and thankful I've been able to have fulfilled these roles and been the custodian of the posts, whether it was here or in the commission. If I look forward, for for the European chemicals agency, I think you have an agency there a competence centre on chemicals that if you give it stability in posts, not in money, because it's its competence lays in the people in the staff. And we need the money to pay the salaries, but money without staff, you can't spend. You have a very competent, very enthusiastic and very, very service oriented organisation where people there are really, really ready to deliver on the European mandate. And I believe that the agency is in a good position now to be able to continue working in this direction, so many, many things.

Pascal Canfin 1:36:28

Thank you, Bjorn. And that would be cancer, free, toxic, free, pollution free. Thank you, from all the members, to you for all what you have done and what you're all what you have been doing, because of course, retirement is closed, but not there yet. So thank you again, for your career, as you said and your commitment. So we move now to the next agenda item meaning the vote the opening of the vote on taxonomy. So we have to wait formally at 415. So there will be a break now and then we will start again. We're under the chairmanship of vice I quit at 445 on the battery text. So see you at 415 for the opening of the vote. I'm thinking I will be alone in the room. Yes, thank you for that and then see what 445

A deeper dive: EP votes on Chemical Strategy for Sustainability

27th July 2020
Environment

I find it useful to look in detail at how the EP votes. It gives a good indication of the political mood of the chamber and their likely future political positions.

The European Parliament voted on their 'Resolution on the Chemical Strategy for Sustainability' on 10 July 2020.

The text was easily carried.

Looking at the excellent VoteWatch (link) the numbers were:

For 579, Against 18, and Abstentions 84

The winning coalition was made up of the GUE, Greens, S&D, Renew, and EPP. Voting loyalty was strong.

Voting against were 12 German AFD members, one Renew member (Frederick Federley), and 3 Dutch ECR members.

A block of 30 abstentions came from the Italian delegation of the IDG group, and one Czech. 51 of the ECR Group abstained.

Group	For	Against	Abstentions	Total present	Total absent	Total non voters	Total members	Cohesion
S&D	141	0	0	141	0	5	146	100
REG	95	1	1	97	0	1	98	96.91
NI	25	2	1	28	0	1	29	83.93
IDG	34	12	30	76	0	0	76	17.11
GUE-NGL	37	0	0	37	0	2	39	100
Greens/EFA	64	0	0	64	0	3	67	100
EPP	176	0	1	177	0	10	187	99.15

Will the Commission listen to the EP on the revision of CLP and REACH?

4th September 2022
Comitology

Re-watching the EP's Environment Committee Exchange of Views on the reform of CLP and REACH (16 May 2022), I was struck by the concerns raised by two members, Arena (S&D) and Hazekamp (Left) on the use of comitology. Patrick Child's (DG ENV) reply is worth listening to.

It will be interesting to see how the Commission takes on board these changes in the upcoming inter-service consultation.

PS: Apologies for the feeble editing.