

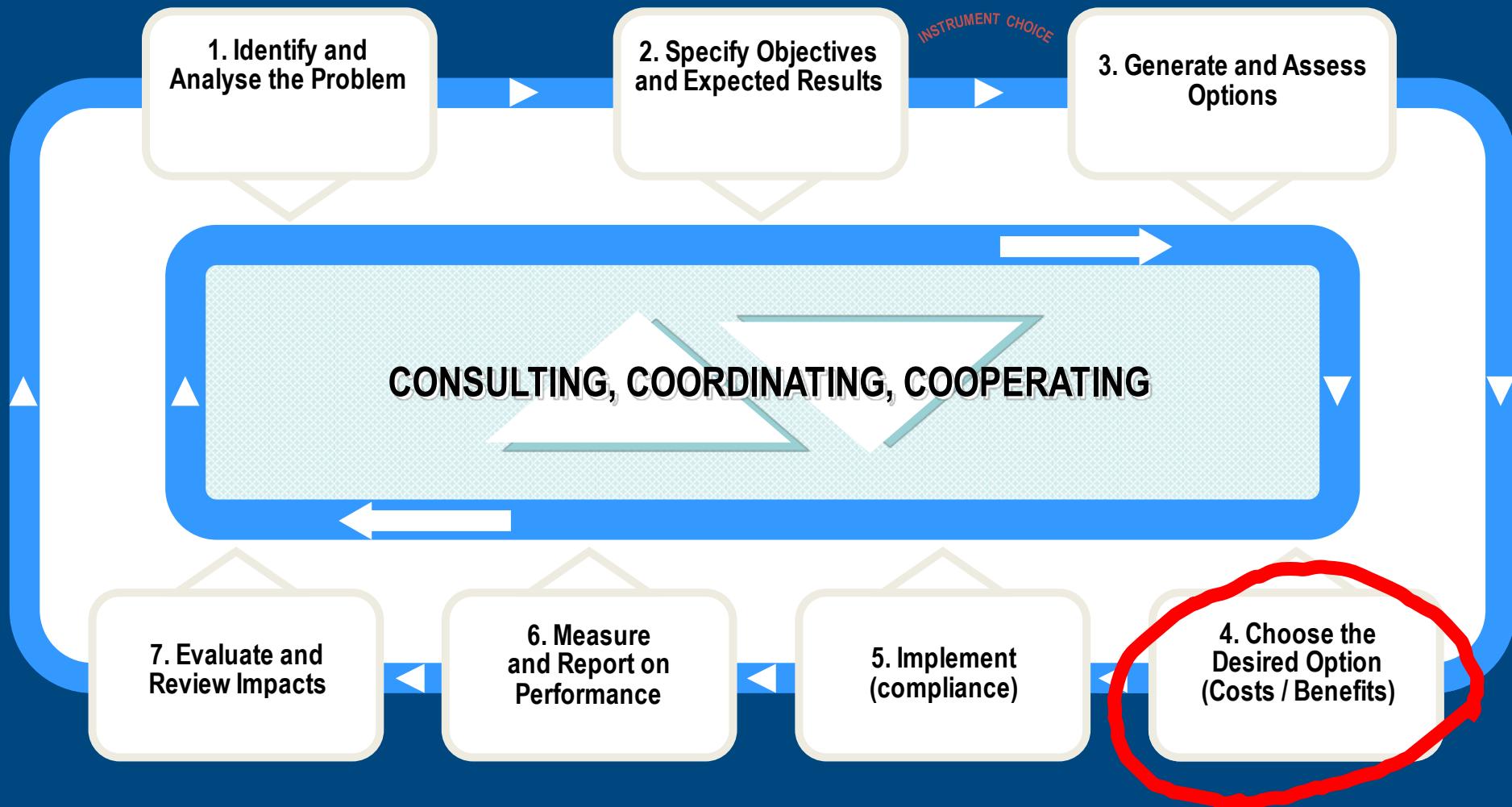
# eRegs the context

(why, who, what)

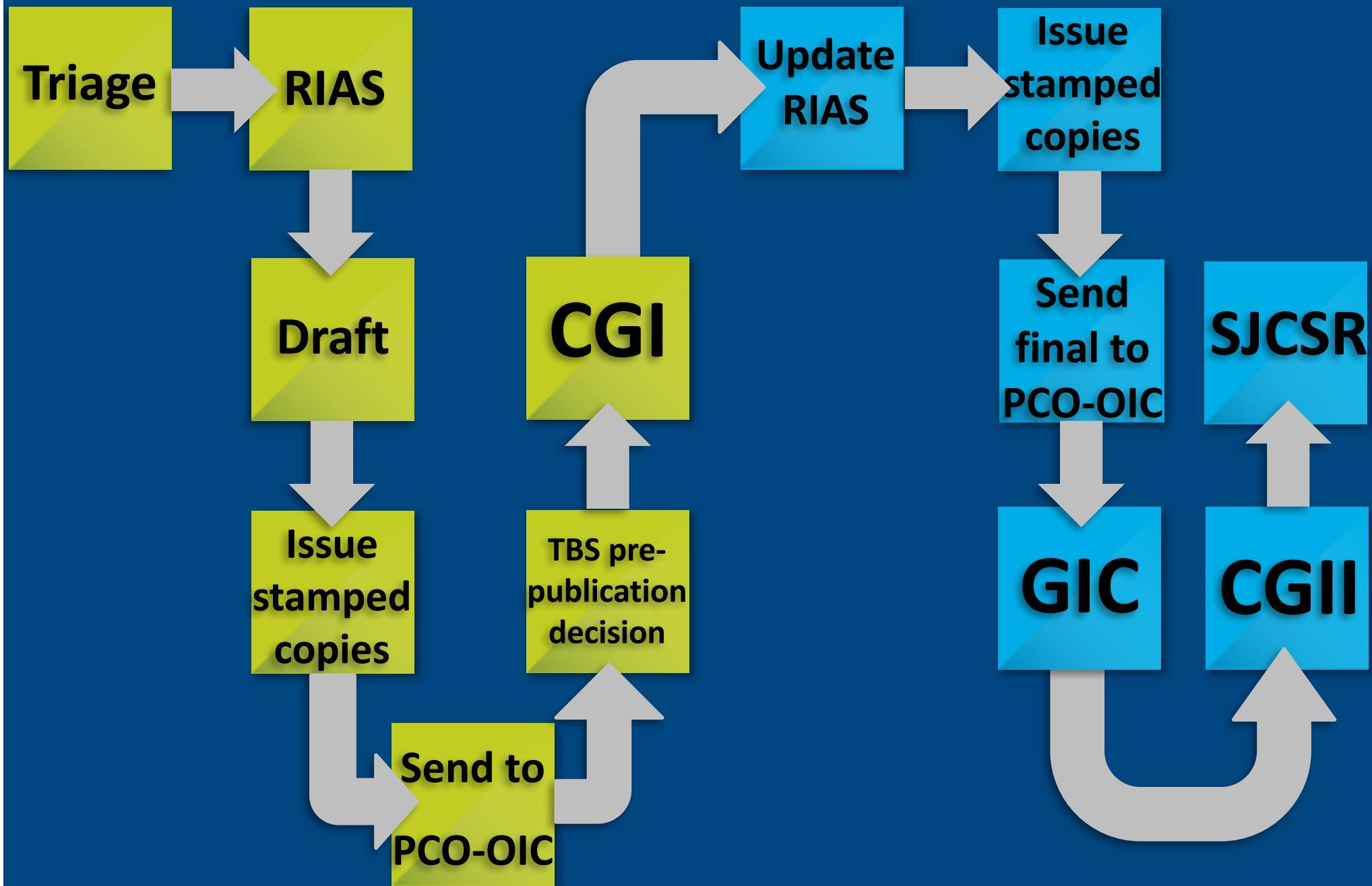
**Ioana Finichiu**  
Community of Federal Regulators  
*@IFiniq*

**Lisa Fast**  
Vation  
*@lisavation*

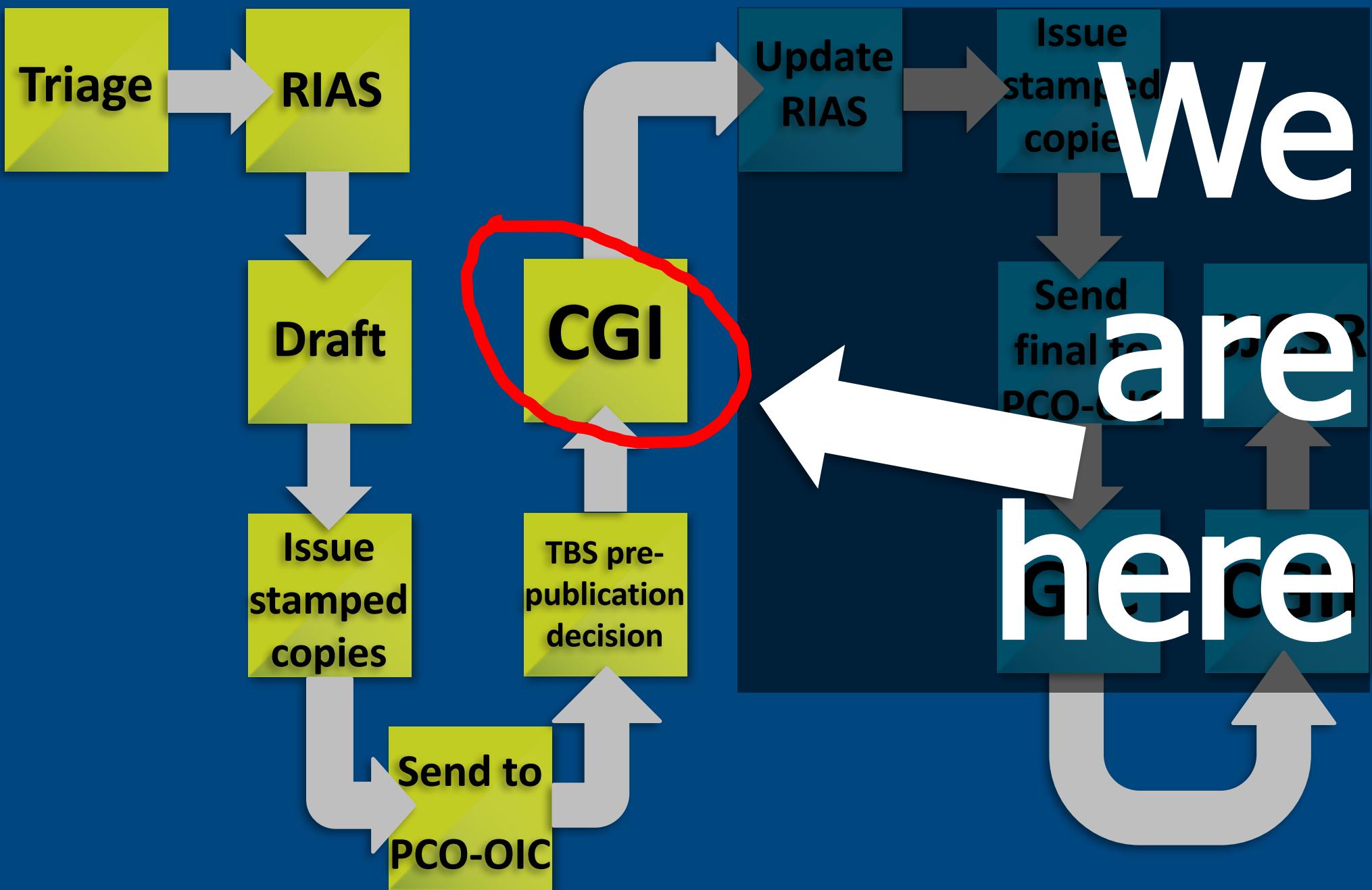
# the regulatory lifecycle



# Federal regulatory development process

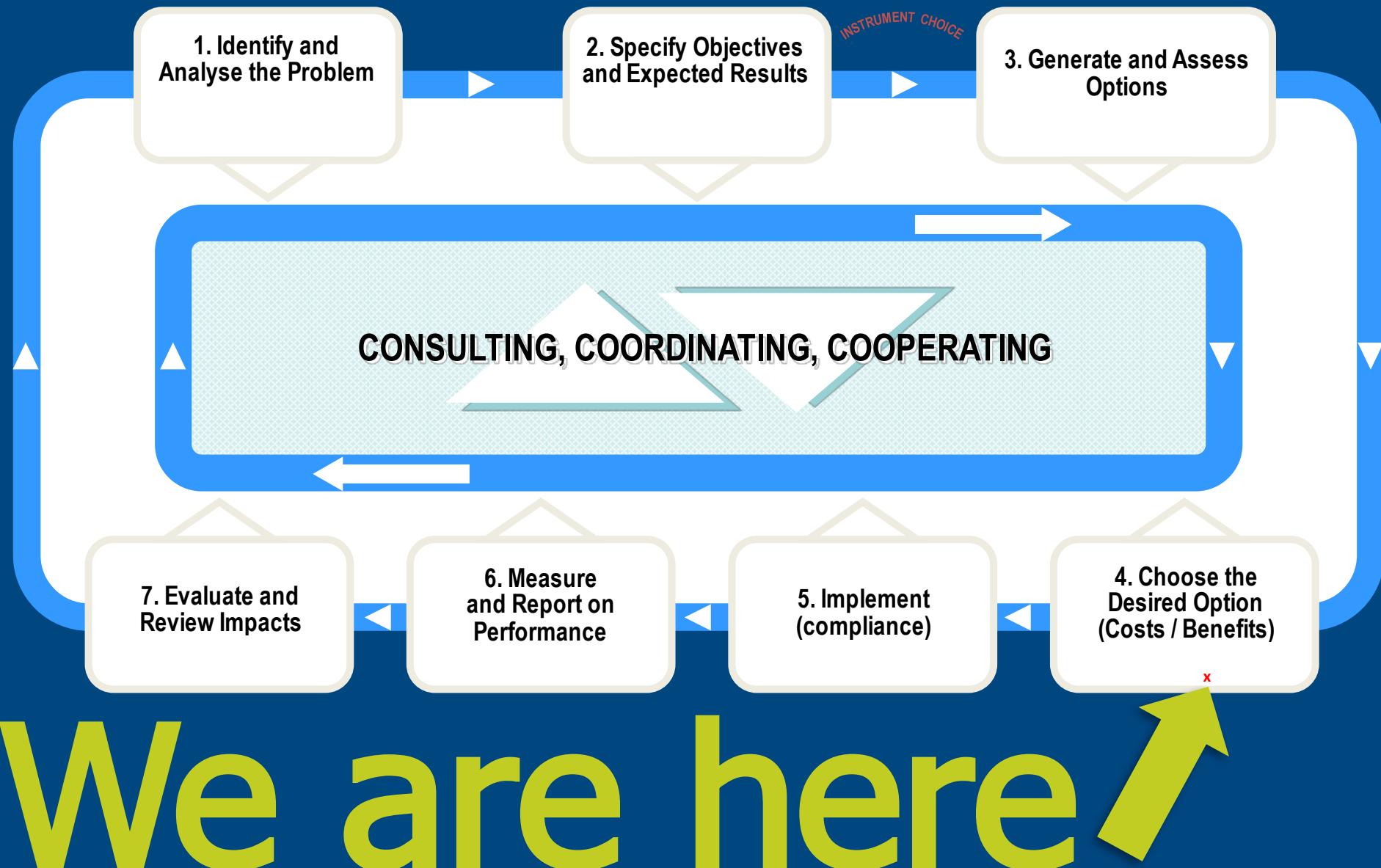


# Federal regulatory development process

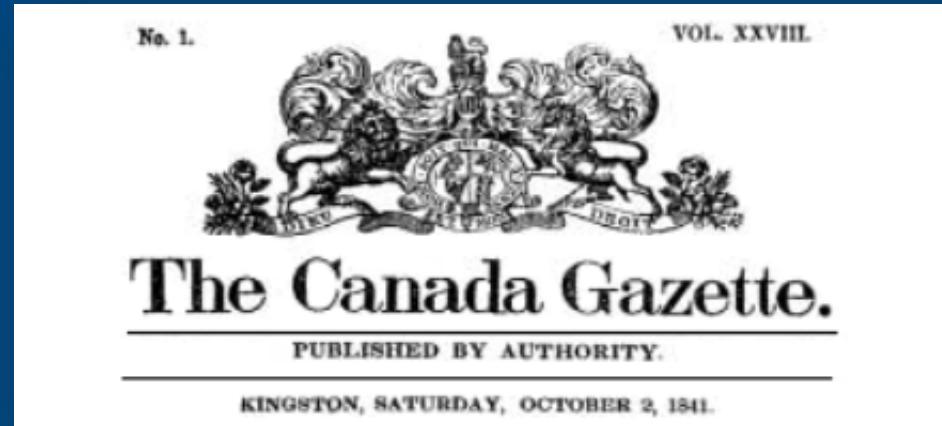


1 step  
of 13 steps  
of the regulatory  
lifecycle

# the regulatory lifecycle



Pre-publication  
*Canada Gazette Part I*



“In serving Canadians for more than a century and a half, the *Canada Gazette* **gives any citizen**, even in the most remote part of the country, **a voice in government decisions** that may affect him or her.”

Vol. 137, No. 14

# Canada Gazette

## Part I

OTTAWA, SATURDAY, APRIL 5, 2003



# Gazette du Canada

## Partie I

Vol. 137, n° 14

OTTAWA, LE SAMEDI 5 AVRIL 2003

### NOTICE TO READERS

The *Canada Gazette* is published under authority of the *Statutory Instruments Act*. It consists of three parts as described below:

Part I Material required by federal statute or regulation to be published in the *Canada Gazette* other than items identified for Parts II and III below — Published every Saturday

Part II Statutory Instruments (Regulations of statutory instruments) — Published weekly on Wednesday

Part III

Since April 1, 2003, the on-line version in Portable Document Format (PDF) of the *Canada Gazette*, Parts I, II and III has the official status and will therefore be published simultaneously with the printed version.

The *Canada Gazette* is also available on the Internet at <http://gazetteducanada.gc.ca>. The publication is accessible in Portable Document Format (PDF) and in hypertext language (HTML) as the on-line PDF format of the *Canada Gazette* since April 1, 2003, and will be published simultaneously with the printed copy.

### NOTICE / AVIS

### AVIS AU LECTEUR

La *Gazette du Canada* est éditée en vertu des dispositions de la *Loi sur les instruments statutaires*. Elle est composée des trois parties suivantes.

Partie I

Depuis le 1<sup>er</sup> avril 2003, la version en direct en format de document portable (PDF) des parties I, II et III de la *Gazette du Canada* a le statut officiel. Il sera publiée en même temps que la version imprimée.

Veuillez noter que tous les numéros en direct publiés avant le 1<sup>er</sup> avril 2003 n'auront pas ce statut officiel.

La *Gazette du Canada* est aussi offerte gratuitement sur Internet au <http://gazetteducanada.gc.ca>. La publication y est accessible en format de document portable (PDF) et en langage hypertexte (HTML) comme média substitut. Le format PDF en direct des parties I, II et III est officiel depuis le 1<sup>er</sup> avril 2003 et sera publié en même temps que la copie imprimée.



# through the years

### Current Consultations in the *Canada Gazette*

The following contains a list of the current proposed regulations about which you are invited to send your comments:

#### Department of the Environment and Department of Health

Proposed Regulations: [Order Adding a Toxic Substance to Schedule 1 to the Canadian Environmental Protection Act, 1999](#)

RIAS: [Regulatory Impact Analysis Statement](#)

Date of publication: [Saturday, November 11, 2017](#)

Number of days for comments: 60 days (Until January 10, 2018)

Contact: Julie Thompson and Michael Donohue

#### Department of Health

Proposed Regulations: [Regulations Amending the Toys Regulations \(Magnetic Toys\)](#)

RIAS: [Regulatory Impact Analysis Statement](#)

Date of publication: [Saturday, November 4, 2017](#)

Number of days for comments: 75 days (Until January 18, 2018)

Contact: Sylvia Weirher

#### Canadian Food Inspection Agency

Proposed Regulations: [Regulations Amending the Agriculture and Agri-Food Administrative Monetary Penalties Regulations](#)

RIAS: [Regulatory Impact Analysis Statement](#)

Date of publication: [Saturday, October 21, 2017](#)

Number of days for comments: 60 days (Until December 20, 2017)

Contact: Executive Director

## **PROPOSED REGULATORY TEXT**

Notice is given that the Governor in Council, pursuant to section 37 of the *Canada Consumer Product Safety Act* ([see footnote d](#)), proposes to make the annexed *Regulations Amending the Toys Regulations (Magnetic Toys)*.

Interested persons may make representations concerning the proposed Regulations within notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publi-

Sylvia Wehrer, Project Officer, Risk Management Bureau, Consumer Product Safety Directorate, Department of Health, Address Locator  
4908B, 269 Laurier Avenue West, Ottawa, Ontario K1A 0K9 (fax: 613-952-2551; [sylvia.wehrer@hc-sc.gc.ca](mailto:sylvia.wehrer@hc-sc.gc.ca)).

Ottawa, October 26, 2017

Jurica Čapkun  
Assistant Clerk of the Privy Council

**be addressed to**

**email:**

is there  
a better  
medium?



web  
application



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of Canada

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## Treasury Board of Canada Secretariat



Community of Federal Regulators  
Communauté des régulateurs fédéraux



Government  
of Canada

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## Department of Justice



Government  
of Canada

Gouvernement  
du Canada

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## Health Canada



Government  
of Canada

Gouvernement  
du Canada

## Canada Gazette

+open

11 October 2017

OGP Announces Government  
of Canada and Nathaniel  
Heller as Lead Co-Chairs for  
2018-19

+transparent

# stakeholders expect it



## Rethinking Citizen Engagement 2017

### Executive Summary

Results from this edition of Rethinking Citizen Engagement reveal a continued and, arguably, strengthened case for increased citizen engagement.

The federal government's 'scorecard' on engagement and consultation is up in a very significant manner, as is trust in the federal government. There is, however, a strong case for further strengthening federal performance in the area of consultations. Although marks are up, performance is still well short of importance; and there are still large portions of the citizenry who are unhappy with government performance in this area (particularly poor marks are assigned to providing Canadians with an opportunity to input into government decision-making). Survey results also reveal that there are still strong reservoirs of negative outlook on government in terms of governments not caring about the views of average citizens, and this cynicism is more prevalent among older and more economically vulnerable Canadians.

The study provides useful guidance on clarifying the boundaries across representative polling and more open consultation. In a nutshell, both are mandatory for different reasons; people want both scientific representativeness and an approach where anyone can show up. The public (outside of Quebec) reject the idea that consultations should be limited to just those with a vested interest in the issue at hand.



HUFFPOST



THE BLOG

## The Changing Rules Of Citizen Engagement

11/17/2016 07:37 EST | Updated 11/17/2016 07:37 EST



KRISTIN AVOLO



Ottawa, Canada

an open government and citizen engagement road  
ister Jean Chretien gave a speech before the  
rnance for the 21st Century in 2000 in Berlin  
he Government of Canada will require new and better  
engaging citizens and civil society in governance. By  
from the Throne stated that the federal government

was committed to a new partnership between government and citizens.

**ultimately...**

input

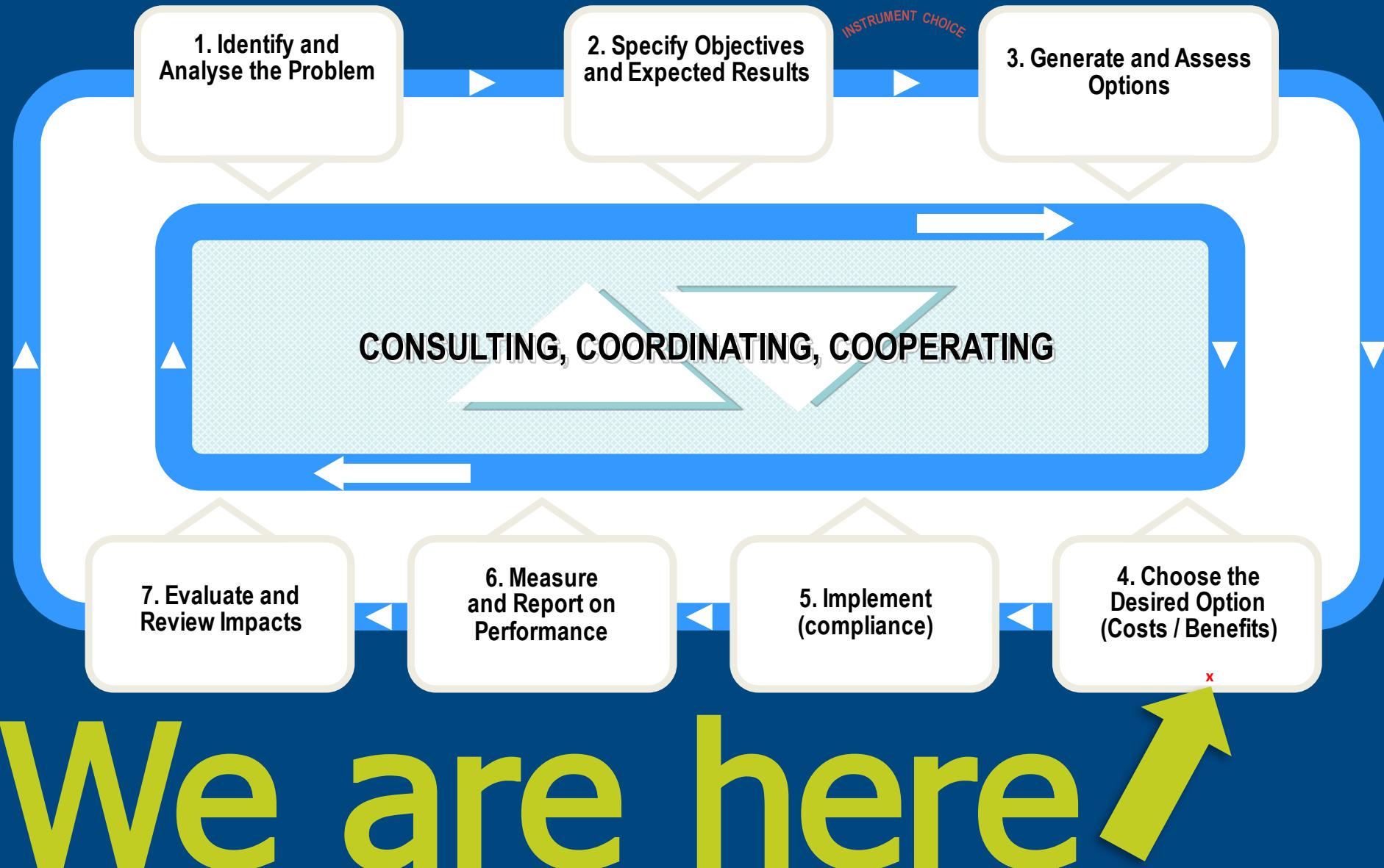
easier

more useful

more focused

more effective  
regulatory  
development

# the regulatory lifecycle



so what  
is this,  
anyways??



# eRegs Pilot Learning

An experimental step towards online  
regulatory consultation and analysis

# Starting Point: US eRegulations -18F Comment Pilot Test in 2016

Read and write with ease



## Read proposed changes in context

See the proposed changes highlighted in comparison to the current regulation at a glance.



## Write responses to individual sections

Respond to sections of the rule, then submit all your responses together as one neatly-organized comment.

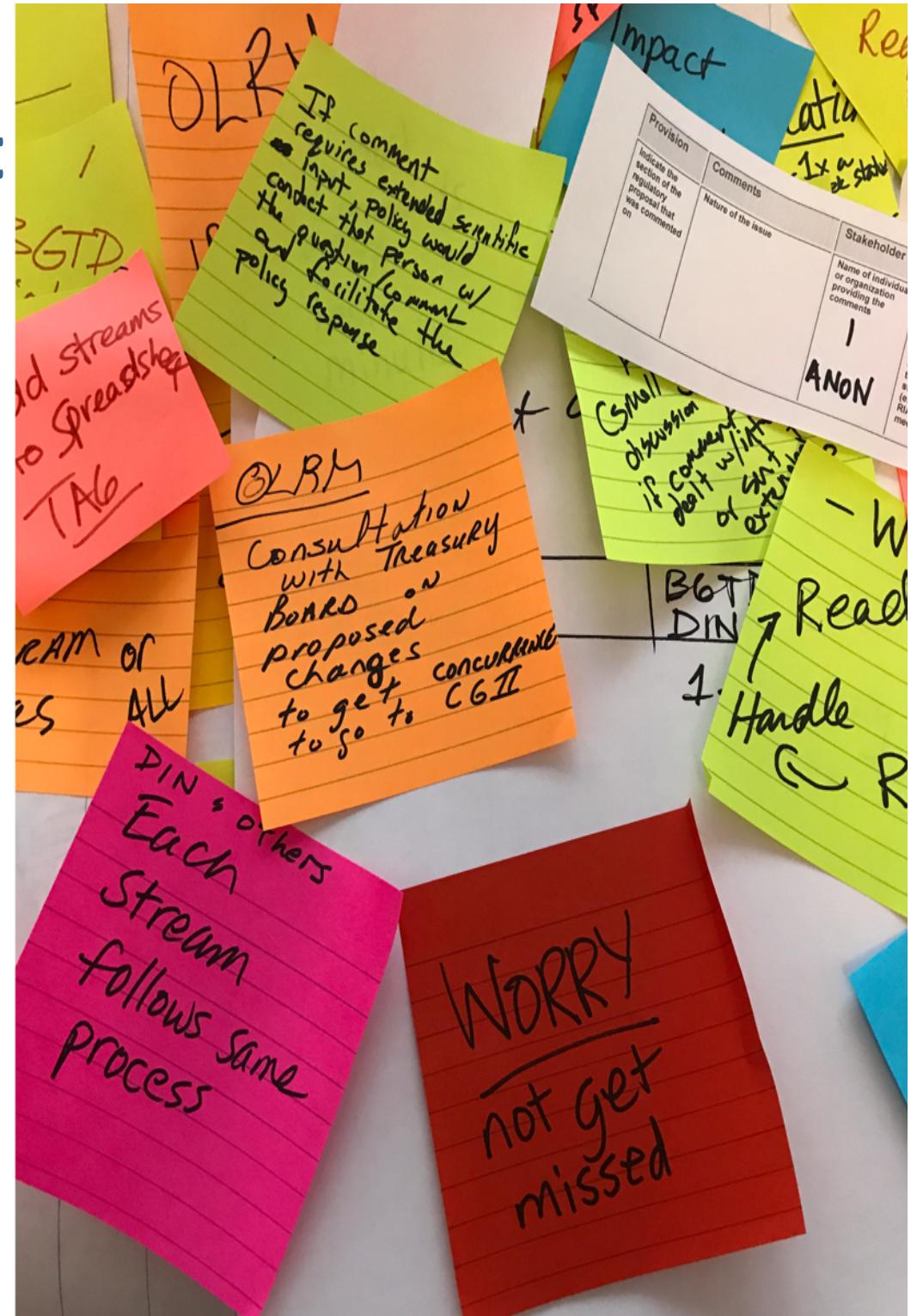


## Help agencies sort & analyze your comment

When you submit your comment, the agency will see which sections you responded to. This helps the agency sort and analyze your comments.

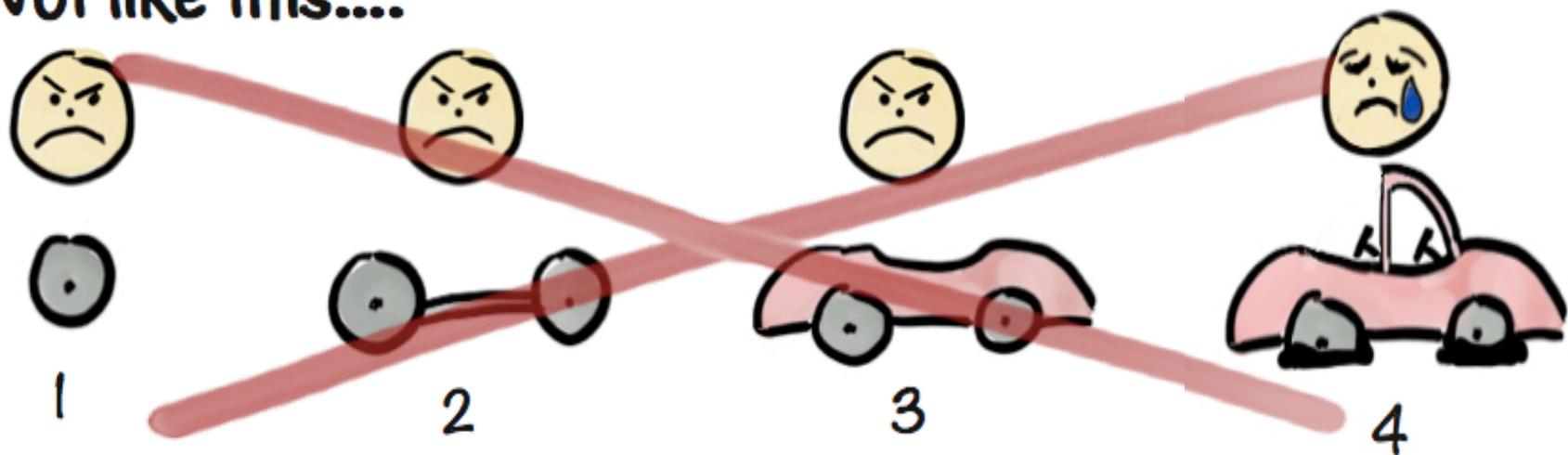
# Core Principles for Pilot

- **User-centred design:** Discovery to understand user needs as you go, validate with users
- **Open source code** – build on existing open-source platforms & microservices, share with national and international community
- **Minimum Viable Product (MVP)** – don't build the whole system, just build a small experimental step to learn, get feedback

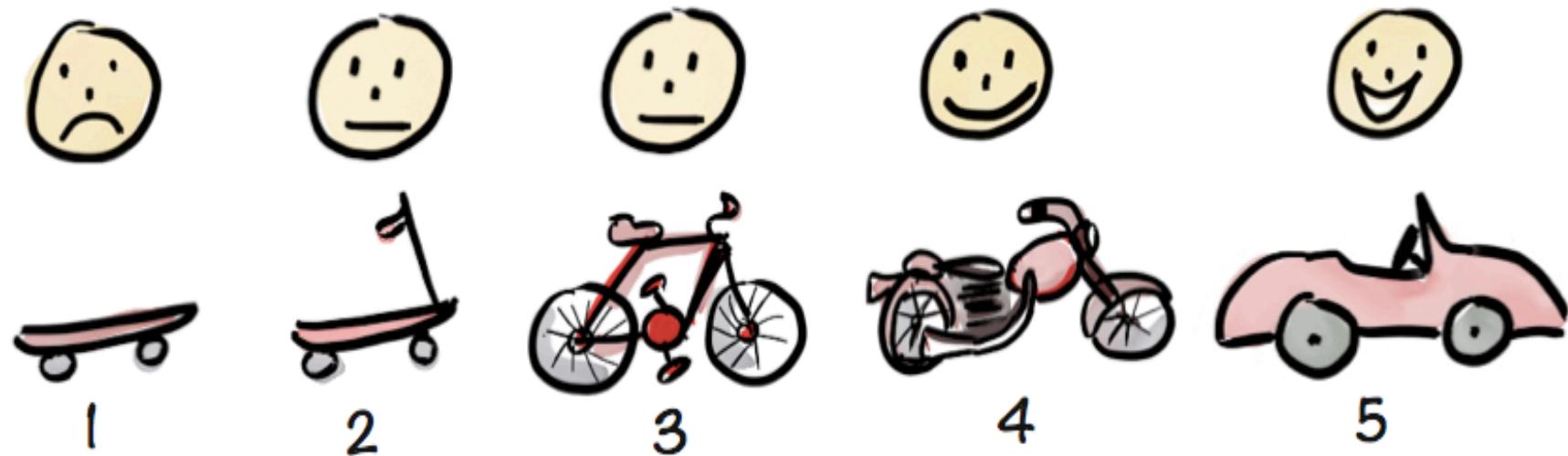


# Minimum Viable Product is an Experiment-based feedback loop

Not like this....



Like this!



# Delivered MVP1 for both faces of regulatory participation

## External Commenter Site

Government of Canada Gouvernement du Canada

Jobs Immigration Travel Business Benefits Health Taxes More services

Home → Acts & regulations

Vol. 151, No. 9 – March 4, 2017

Regulations Amending the Food and Drug Regulations and the Regulations Amending the Food and Drug Regulations (Shortages of Drugs and Discontinuation of Sale of Drugs)

Statutory authority  
Food and Drugs Act

Sponsoring department  
Department of Health

Provide your comments

Select the point of view you best represent (required)  
-- Select --

Your name

Name of the organization you represent

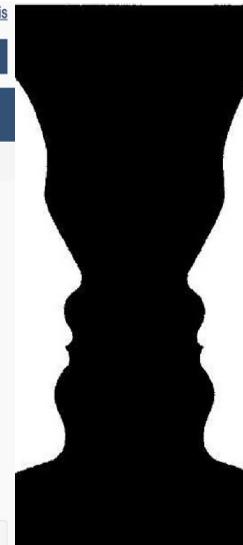
Your email address  
Provide your email to allow communications about your comments.

Your privacy

Highlighted comment boxes are provided in the Regulatory Impact Analysis Statement and in the Proposed Regulatory text below.

[Skip to first comment box](#)

[View summary](#) [Submit your comments](#)



## Internal Analysis Toolkit

Section	Comment	Notes
ris-10 Issues	Test 1	<a href="#">Note +</a>
ris-10 Issues	Test 1 Test 2.a	<a href="#">Note +</a>
ris-22 Background	We are in full agreement with the introduction of the new status of "dormant". With respect to the process, it is stated in the guidance that "If subsequent to notifying Health Canada of the period without sale, the manufacturer determines that they will resume sale of the product on the Canadian market they must within 30 days after commencing sale of the drug, a signed and dated Drug Notification Form (DNF)..." If we've marketed a product we would have already submitted a signed DIN Form with date of first sale. So what DIN Form are we to use when we resume sales? The Regs just say to provide written notification. Will Health Canada provide a new blank DIN Form, when we notify of going Dormant, that we could complete with a new first sale date?	<a href="#">Note +</a>
ris-27 Objectives	The Sponsor supports the initiative and appreciates the opportunity to comment. This initiative enhances drug access for patients and we would like to give emphasis to the importance of expediting this amendment.	<a href="#">Note +</a>

# User-centered design – online sessions with external stakeholders

Iterative design improvements during development

First online research sessions with association stakeholders started soon after contract signing  
- user-centered design

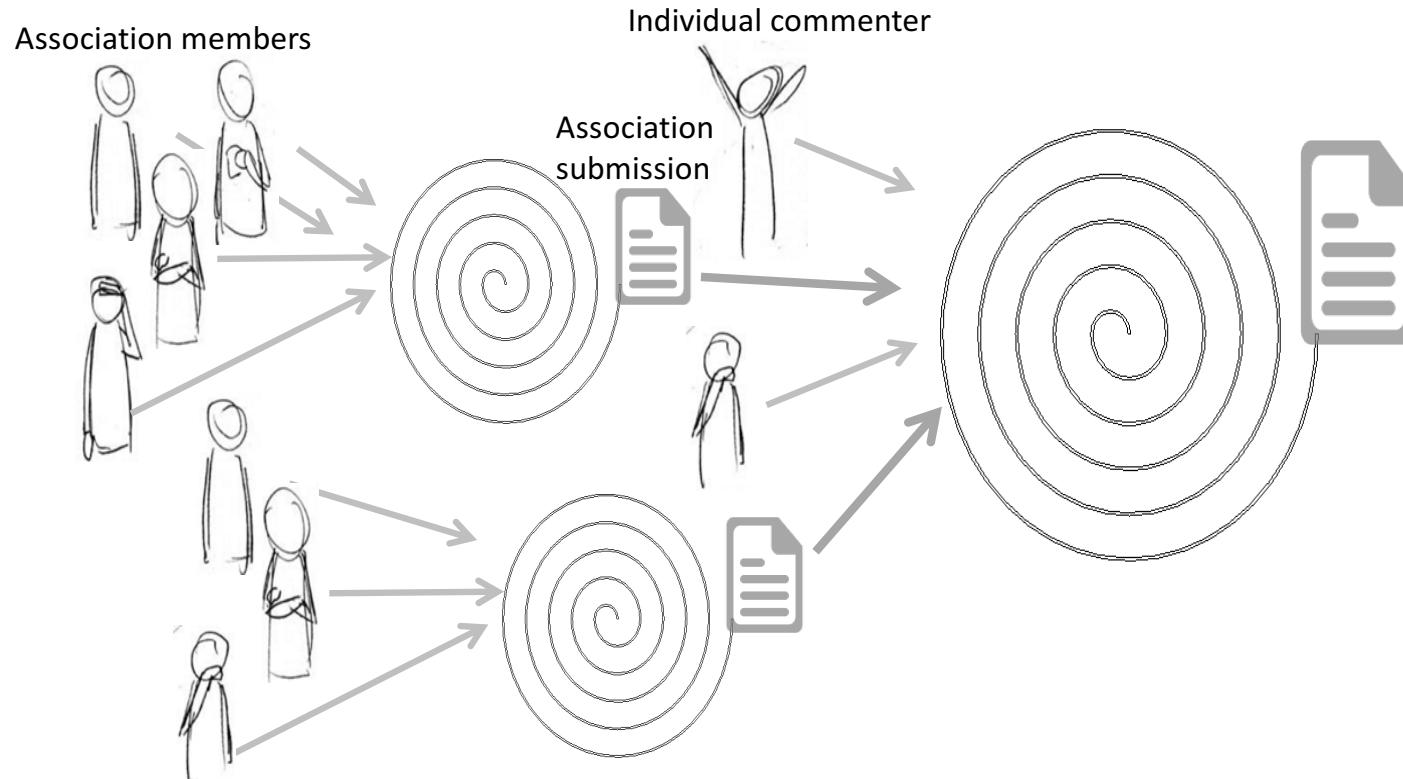
Research highlights video: [https://youtu.be/T\\_iAA3ydtEM](https://youtu.be/T_iAA3ydtEM)

The image shows a user-centered design interface for collecting comments from external stakeholders. It consists of two main sections:

- Section 1:** A light blue header bar contains the text "is considered earnings for the purposes of section 35." Below it is a yellow box with a blue border containing a blue downward arrow and the text "Comment on Subsection 38(2)". Inside this box is a text area with the placeholder "A test comment on section 38....". At the bottom are two buttons: "Close" and "Submit all comments".
- Section 2:** A light blue header bar contains the text "Add your comments on These Regulations, except sections 19 to 21". Below it is a yellow box with a blue border containing a blue downward arrow and the text "(2) Sections 19 to 21 come into force on the day on which these Regulations are registered." Inside this box is a text area with the placeholder "Test comment about section 20". At the bottom are two buttons: "Save" and a green checkmark icon followed by the text "Comment saved".

# Associations Perform Same Share-Receive-Analyze Process

Just like government, associations gather member comments, review & synthesize the comments into a submission - **need support & integration, not add-on copy/paste work**



Participant 2: “*So I could send them a link to see our actual submission- I like that idea as long as it was easy for them to do*”.

Participant 4: “*if we could do this, would we even keep a Word copy? Because it’s tedious... this could streamline our process*”

# On-time launch of Comment Pilot in French & English

► [Add your comments on These Regulations, except sections 19 to 21](#)

(2) Sections 19 to 21 come into force on the day on which these Regulations are registered.

► [Add your comments on Sections 19 to 21](#)

[9-1-0]

Site launched on-time on March 4<sup>th</sup> simultaneous with Gazette on-line launch of the proposed amendment

 [Footnote 1](#)

<http://www.gazette.gc.ca/rp-pr/p2/2016/2016-06-29/html/sor-dors139-eng.php>

[Footnote 2](#)

<https://www.nrcan.gc.ca/energy/uranium-nuclear/7793>

[Footnote a](#)

S.C. 2012, c. 19, s. 414

[Footnote b](#)

R.S., c. F-27

[Footnote 3](#)

C.R.C., c. 870

[Commenting site](#)

<https://dev.regconsultation.ca:8080/>

Video demo of commenting site:

<https://youtu.be/jdfhSThtA-c>

## View summary and submit your comments

[View summary](#)

[Submit your comments](#)

# Internal Discovery: Kicked off with team workshop to discover various roles, user needs & pain points in current process



**Prepare**   **Gazette**

**Receive**  
(Reg Management)  
Worry: lose a  
comment  
or lose track of a  
comment

**Analyze**  
(Programs)  
Worry: miss an  
important comment  
or issue

**Review**  
(all and TBS)

# Process from Discovery Maps Onto Key Tasks in Toolkit

## Consultation Toolkit – Receive Commentaries

Signed in as Lisa Fast

[Account settings](#)

[Sign out](#)

Prepare documents

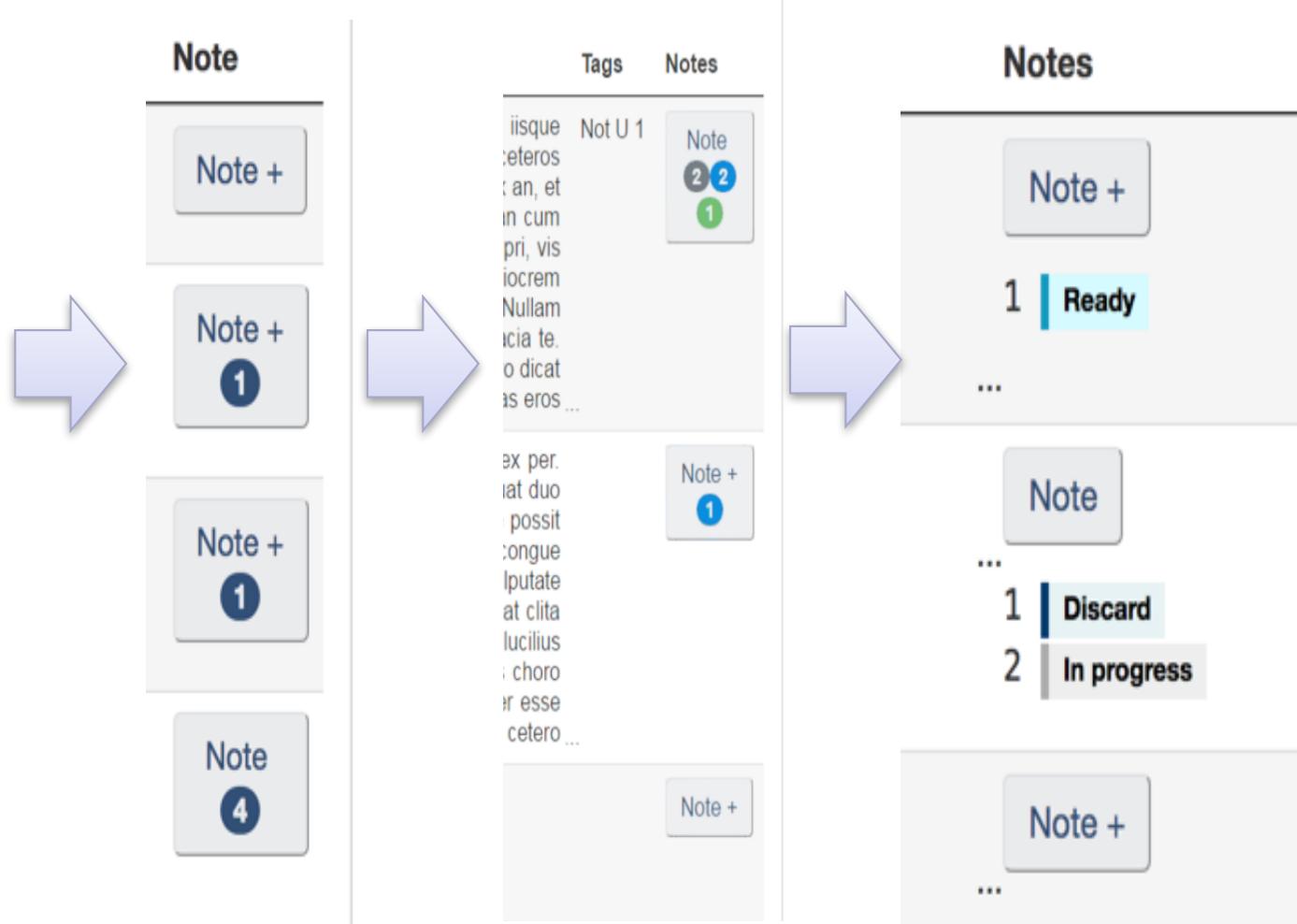
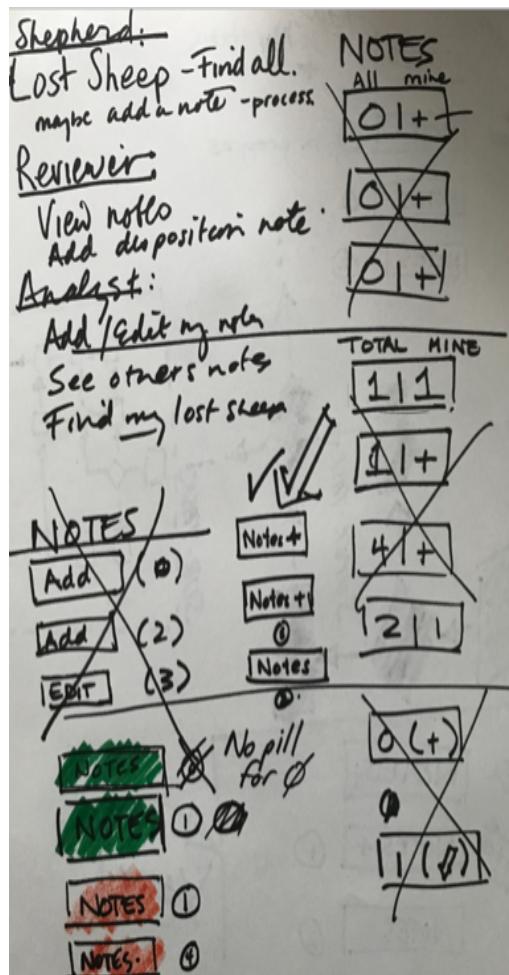
Receive commentaries

Make notes

Review and decide

# Consultation Toolkit MVP co-designed with Health Canada team

Sketching, review discussions & usability sessions with HC Team



# Toolkit: Review and Make Notes to analyze & resolve comments

2017-DINS-radiopharmaceuticals

## All comments

Filter items 3 | Showing 1 to 4 of 4 entries (filtered from 12 total entries) | Show 10 entries

Section	Comment	Note summary	Notes
ris-22 Background	<p>We are in full agreement with the introduction of the new status of "dormant".</p> <p>With respect to the process, it is stated in the guidance that "If subsequent to notifying Health Canada of the period without sale, the manufacturer determines that they will resume sale of the product on the Canadian market they must within 30 days after commencing sale of the drug, a signed and dated Drug Notification Form (DNF)..."</p> <p>If we've marketed a product we would have already submitted a signed DIN Form with date of first sale. So what DIN Form are we to use when ...</p>		<button>Note +</button>
ris-22 Background	<p>On June 14, 2016, Regulations Amending the Food and Drug Regulations (Shortages of Drugs and Discontinuation of Sale of Drugs) – Canada Gazette Part II, Volume 150, No. 13 was published with a coming into force date nine months after publishing. These regulations required authorization holders (DIN Owners / Manufacturers) to notify the Minister if a period of 12 months has elapsed since an authorization holder for a drug last sold the drug, within 30 days after the day on which that period ends. The regulations also required ...</p>		<button>Note +</button>
ris-35 Labelling Requirements	<p>C.01A.005 states: "A person who wishes to apply for an establishment licence shall submit an application to the Minister, in a form established by the Minister, that contains the following information and documents: (i) the drug identification number, if any, or a name that clearly identifies the drug,"</p>	<p><span>Decision</span> Comment rescinded at source</p>	<p><span>Note +</span> 1   <span>Decision</span></p>

# What we learned

# Learning: New services often require new policies



**Net neutrality: 'Dead people' signing FCC consultation - BBC News**  
Campaigners say 'hundreds' have complained about their details being used to post fake comments.

[bbc.com](http://bbc.com)

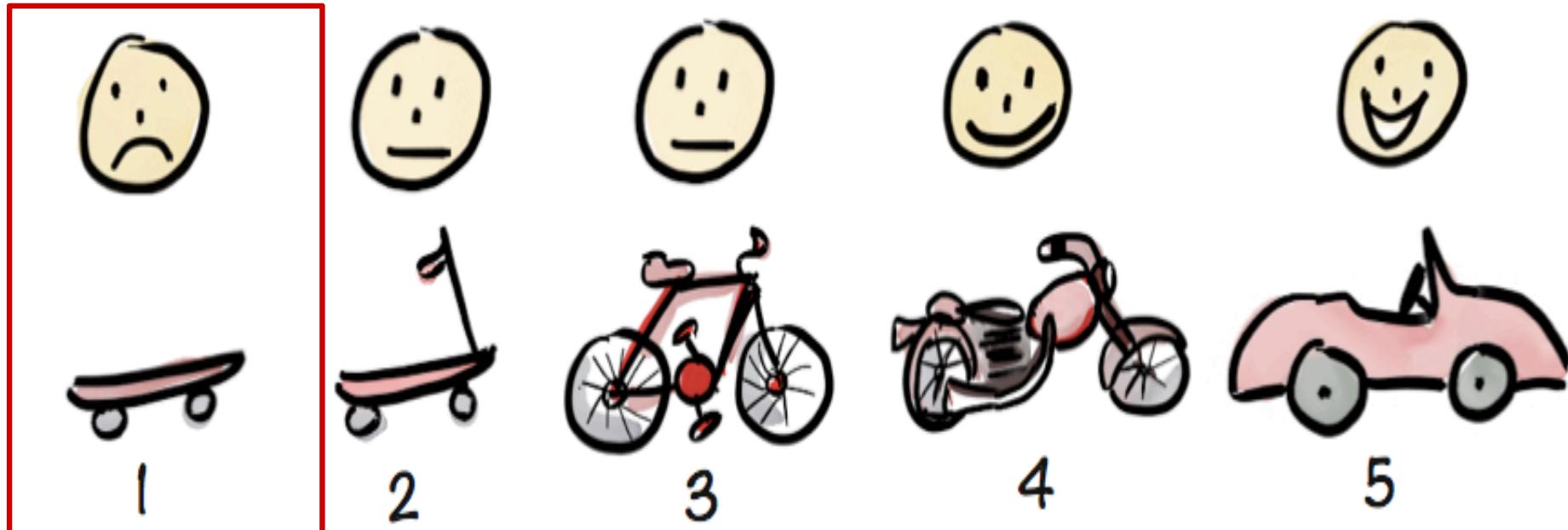
Decision taken to allow anonymous submissions in the pilot.

- Association objected but decision was made to allow them because in theory, someone now could send an anonymous email
- Need better way to set policy for new online designs because of bots & trolls & different behaviour models

<https://medium.com/@AGSchneiderman/an-open-letter-to-the-fcc-b867a763850a>

Next decision – Attribution – show comments to public (& who made them)

# External Stakeholders may have different definition of ‘minimal’

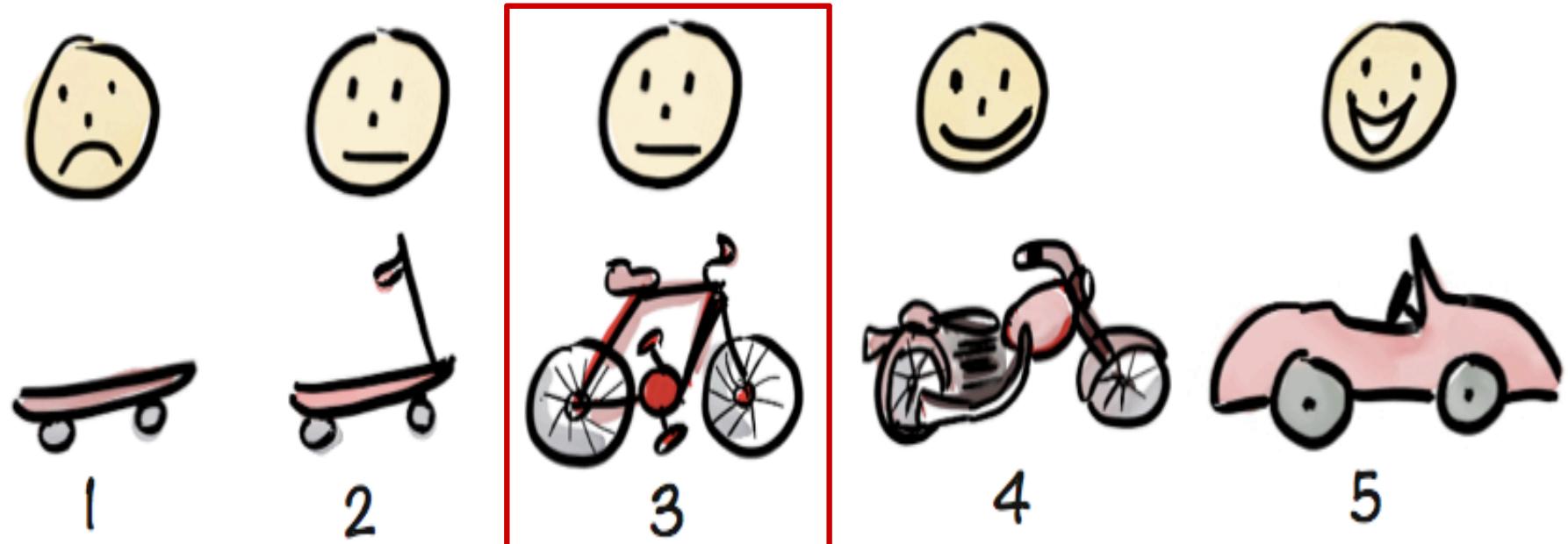


Participant 1: *"I get that this is much better for the government, then it's all laid out in a table for them... But it creates more work for me. It's a second layer – I put it in a table and say hey members, send out a table to them and get them to do it. There's no save and share option here."*

- Result: Only 1 of 5 association stakeholders submitted their comments online – the rest stuck to email – the HC team entered their emailed comments into the system themselves

**Learning: Individual commenters and associations may have different needs**

# Analysis toolkit had more discovery time – got farther



Got closer to meeting needs of receivers, analysts and reviewers – co-created site with them

*“I definitely think we are headed in the right direction – Very supportive of proceeding”*

*“I’m supportive of proceeding with changes to terminology, documentation and reporting”.*

All consultations entered online - team performed analysis & review on the Toolkit  
Lots of unimplemented bits – preparation of the document for launch was done by hand



Alex Benay

CIO Government of Canada Soon to be author PhD Candidate, Leicester University

3d

...

I think we... as government... have to get immensely better at failing. Learning to fail properly is one of the biggest blind spots we have as the Government of Canada.

226 Likes • 66 Comments

## Lesson: Small experiments avoid big failures