

All your answers to questions in sections 2, 3 and 4, are intended to be published on the web, together with some of your personal data (please read the specific privacy statement before answering the following questions). Please note that answers to questions

1.1. Your full name: 1.7. I'm replying as a(n):

1.7.a.If replying as an individual/citizen/consumer, please specify if your reply is based on your knowledge acquired in your working environment (e.g. private company, NGO, public institution, research) or on general interest:

Under the name supplier Australian Government b. On behalf of an organ

Anonymously (I consent SILUE GNENEYERI b. On behalf of an organ

Under the name supplier Chris LEGGETT b. On behalf of an organ
Under the name supplier Lars Juergensen b. On behalf of an organ
Under the name supplier Claudia Mónica Cabeza b. On behalf of an organ
Under the name supplier MINISTÉRIO DA AGRIC b. On behalf of an organ
Under the name supplier John Reeve on behalf of b. On behalf of an organ

Under the name supplier Ministerio de Relaciones b. On behalf of an organ

Under the name supplier Tania De Belder b. On behalf of an organ
Anonymously (I consent Christopher Kanema b. On behalf of an organ

Under the name supplier Annika Hanberg b. On behalf of an organ

1.7.a.ii. If you selected working environment, please specify:	1.7.b.1. If responding on behalf of a(n) organisation/association/authority/company/body, please provide the name:	1.7.b.2. Is your organisation listed in the EU transparency register?
	Australian Government	c. Do not know
	Direction de la protection des végétaux, du contrôle et de la Qu	b. No
	Government of Canada Health Canada INSTITUTO COLOMBIANO AGROPECUARIO - ICA MINISTÉRIO DA AGRICULTURA, PECUÁRIA E ABASTECIM Ministry for Primary Industries, Environmental Protection Autho	b. No c. Do not know b. No c. Do not know b. No
	República Argentina	b. No
	United States Government Zambia Environmental Management Agency	b. No c. Do not know
	Institute of Environmental Medicine, Karolinska Institutet	c. Do not know

1.7.b.2.a. Please specify identification number (optional):	1.7.b. Please specify the organisation you represent:	1.7.b.i. If public authority, please specify:	1.7.b.i.(3). If government authority, please specify:
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	i. Public authority	(3) Government authority	National
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	i. Public authority	(3) Government authority	National
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	i. Public authority	(3) Government authority	National
	i. Public authority	(3) Government authority	National
	i. Public authority	(3) Government authority	National
	i. Public authority	(3) Government authority	National
	i. Public authority	(3) Government authority	National

	i. Public authority	(3) Government authority	National
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	i. Public authority	(1) International institutio	
	i. Public authority	(3) Government authority	National

	ii. Academic/Research ir		
--	--------------------------	--	--

1.7.b.ii. If Academic/Research institution, please specify:	1.7.b.iii. If hospital/health institution, please specify:	1.7.b.iv. If private company, please specify size:	1.7.b.vi(1). If consumer/non-governmental organisation, please specify members:
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University (including teach

1.7.b.vi(2). If consumer/non-governmental organisation, please specify actions:	1.7.b.vi(2): If other, please specify.	1.7.b.vii. If industrial or trade association, please specify:	1.7.b.viii. If other, please specify.
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1.11. Were you or your organization directly involved in/affected by the EU legislation mentioned below in the past 3 years? (more than one answer possible)

If other, please specify.

1.12. In what context have you been made aware of the discussions about endocrine disrupting chemicals?

2.1.1. Have you conducted or are you aware of an assessment of substances which would be identified as endocrine disruptors according to option 1?

Classification and Labelling

As part of my profession Yes

Not involved

As part of my profession No

Classification and Labelling
Classification and Labelling
Plant Protection Product
Not involved
Classification and Labelling

New Zealand is directly involved

As part of my profession Yes
As part of my profession Yes
As part of my profession No
Media for the general public No
As part of my profession Yes

Classification and Labelling

As part of my profession No

REACH (Regulation 1907/2006)
Classification and Labelling

As part of my profession No
Scientific publications No

Not involved

As part of my profession No

**If yes, please
describe the
methodology(ies):**

**If yes, please
describe the
outcome(s) of the
assessment(s):**



Although Australia has re Australia welcomes the opportunity to participate in the European Union's p

*Note: While Health Can The outcome of each ch [85eb9c96-8046-4cce-9971-38f31843a57f/Respo](#)

*Note: While Health Can The outcome of each ch [1c8c871d-c982-4a37-8478-4062b06bd61d/Respi](#)

*Note: Because New Ze The HSNO classifications for carcinogenicity, reproductive toxicity and targ

Please provide the reference(s) if possible

public consultation process on defining criteria for identifying endocrine disruptors. This is a complex

[nse to 2.1.1 Additional Clarification.pdf](#)
[onse to 2.1.1 Additional Clarification.pdf](#)

et organ toxicity (equivalent to classification under GHS chapters 3.6, 3.7 and 3.9) are used to deter



2.1.2. Are you aware of any assessment(s) of substitutability of the identified substances?	If yes, please describe the methodology(ies):	If yes, please describe the outcome(s) of the assessment(s):
area of policy development	Yes	Australia maintains a risk Australian chemical regu
	No	
	Yes	As per Canadian pesticid
	Yes	For those chemicals whe
	No	As per Canadian pesticid
	No	For those chemicals whe
mine the requirements fo	No	
	No	
	No	
	No	

Please provide the re

latory agencies would concur with the 2013 opinion of the Scientific Committee (SC) of the Europea

ere exposure is below the level of concern for dietary and environmental exposures, and where targe
ere exposure is below the level of concern for dietary and environmental exposures, and where targe



ference(s) if possible

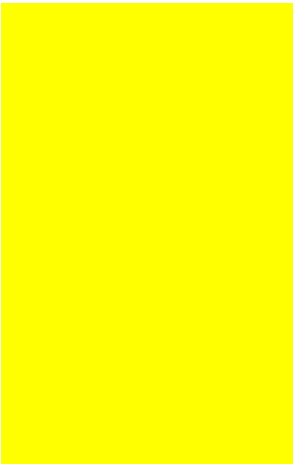
in Food Safety Authority (EFSA) that “to inform on risk and level of concern for the purpose of risk m

t Margins of Exposure are achieved for non-dietary exposures, the health risks are considered acce;
t Margins of Exposure are achieved for non-dietary exposures, the health risks are considered acce;

2.1.3. Are you aware of any assessment(s) of the socio-economic impact if the identified substances were regulated without further risk assessment?

If yes, please describe the methodology(ies):

If yes, please describe the the outcome(s) of the assessment(s):



Yes

Common Technical Polic Please see responses to 2.1

No

Yes
No
No
No
No

Implications of adopting Any change to the EU's scientific assessment for

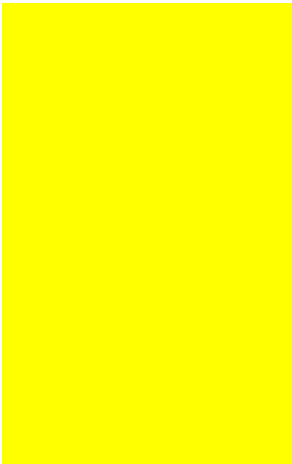
No

No
No

No

Please provide the reference(s) if possible

n risk- to hazard-based criteria would likely result in the de-listing of a variety of Plant Protection Pro



2.1.4. Please, provide us with any other comments you may have regarding option 1:	2.2.1. Have you conducted or are you aware of an assessment of substances which would be identified as endocrine disruptors according to option 2?	If yes, please describe the methodology(ies):
--	--	---

The use of 'carcinogenic Yes	Please see responses in
------------------------------	-------------------------

Se référer aux propositio No

ducts (PPPs) that are ex	Endocrine disrupting che Yes	See response to 2.1.1.
	Yes	See response to 2.1.1
	No	
	No	
New Zealand regulators	No	

Dado que la normativa a No

This option only determin No
No

The Institute of Environrr No

**If yes, please
describe the
outcome(s) of the
assessment(s):**



Please see responses in 2.1

See response to 2.1.1.
See response to 2.1.1

Please provide the reference(s) if possible:

If yes, please describe the outcome(s) of the assessment(s):

Please provide the reference(s) if possible:

2.2.3. Are you aware of any assessment(s) of the socio-economic impact if the identified substances were regulated without further risk assessment?

If yes, please describe the methodology(ies):

Please see responses in 2.1

Yes

Please see responses in

No

See response to 2.1.2.
See response to 2.1.2

Yes
No
No
No
No

See methodology under

No

No
No

No

If yes, please describe the outcome(s) of the assessment(s):

Please provide the reference(s) if possible

2.2.4. Please, provide us with any other comments you may have regarding option 2.

2.3.1. Have you conducted or are you aware of an assessment of substances which, in addition to those identified according to option 2, would be identified as suspected endocrine disruptors or endocrine active substances (Categories II or III)

Please see responses to 2.1

According to this definitic Yes

Se référer aux propositic No

See outcome of assessment under 2.1.3.

See other comments un No
No
No
No
For the reasons outlined No

Dado que la normativa a No

Policy Option 2 for Aspe No
No

The Institute of Environrr No

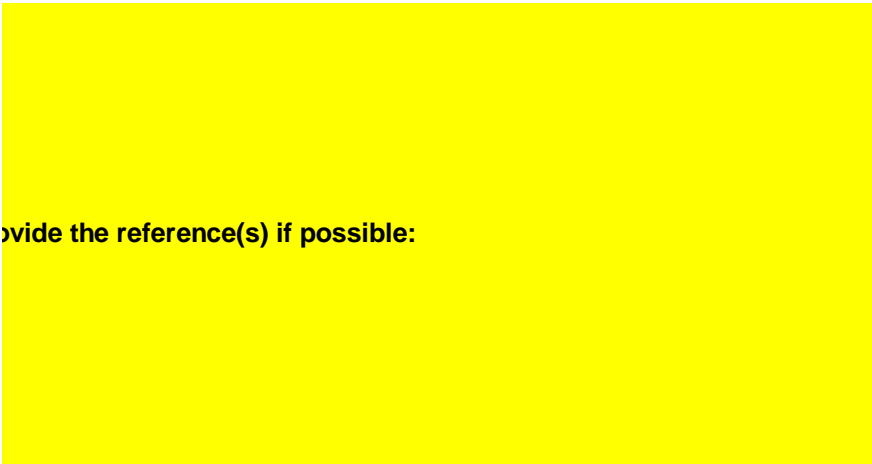
**If yes, please
describe the the
methodology(ies):**

**If yes, please
describe the
outcome(s) of the
assessment(s):**



Please pro

Please see responses in Please see responses in 2.1



Provide the reference(s) if possible:

2.3.2. Are you aware of any assessment(s) of substitutability of the identified substances?

Yes

No

No
No
No
No
No

No

No
No

No

**If yes, please
describe the the
methodology(ies):**

**If yes, please
describe the
outcome(s) of the
assessment(s):**

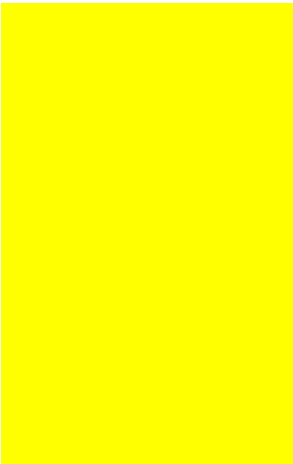
Please provide the reference(s) if possible:

Please see responses in Please see responses in 2.1

2.3.3.Are you aware of any assessment(s) of the socio-economic impact if the identified substances were regulated without further risk assessment?

If yes, please describe the methodology(ies):

If yes, please describe the outcome(s) of the assessment(s):



Yes

Please see responses in Please see responses to 2.1

No

Yes
No
No
No
No

See methodology under See outcome of assessment under 2.1.3.

No

No
No

No

Please provide the reference(s) if possible:

<p>Please, provide us with any other comments you may have regarding option 3.</p>	<p>2.4.1. Have you conducted or are you aware of an assessment of substances which would be identified as endocrine disruptors according to option 4?</p>	<p>If yes, please describe the methodology(ies), including the potency thresholds that applied:</p>	<p>If yes, please describe the outcome(s) of the assessment(s):</p>
--	---	---	---

Proposed categories (bæ Yes	The EU Plant Protection Industrial chemicalsPhthæ
-----------------------------	---

Se référer aux propositioic No

See other comments unæ Yes	See response to 2.1.1 P	See response to 2.1.1.
Yes	See response to 2.1.1 A	See response to 2.1.1
No		
No		
For the reasons outlined No		

Dado que la normativa a No

The EC's own initial assæ No
No

The Institute of Environrr No

Please provide the reference(s) if possible:

alates and BFRs: The most relevant examples of recent NICNAS assessments of chemicals with en

2.4.2. Are you aware of any assessment(s) of substitutability of the identified substances?	If yes, please describe the methodology(ies):	If yes, please describe the outcome(s) of the assessment(s):	Please provide the ref
---	---	--	------------------------

Yes	Please see responses to	Please see responses to 2.1	
-----	-------------------------	-----------------------------	--

No

Yes	See response to 2.1.2.	See response to 2.1.2.	
Yes	See response to 2.1.2	See response to 2.1.2	
No			
No			
No			

No

No
No

No

ference(s) if possible:

2.4.3. Are you aware of any assessment(s) of the socio-economic impact if the identified substances were regulated without further risk assessment?

If yes, please describe the methodology(ies):

If yes, please describe the outcome(s) of the assessment(s):

Yes
Please see responses to

No

Yes
See methodology under
No
See outcome of assessm
No
No
No
No

No

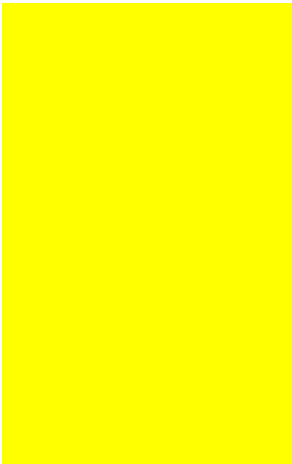
No
No

No

Please provide the reference(s) if possible:

2.1

ment under 2.1.3.



2.4.4. Please, provide us with any other comments you may have regarding option 4.

3.1. Have you conducted or are you aware of an assessment applying any of the 3 different options for regulatory approaches to decision making (option A-C) to substances identified as endocrine disruptors by any of the options for defining criteria

If yes, please describe the methodology(ies)

As noted in the commen Yes

Please see responses to

Se référer aux propositio No

See other comments un Yes
Yes
No
Identifica-se, como a m No
While New Zealand doe Yes

As noted in 2.1.1., Healt
As noted in 2.1.1., Healt

As stated in para 2.1.1, t

Dado que la normativa a No

Policy Option 4 for Aspe Yes
No

Please see U.S. comme

The Institute of Environrr No

**If yes, please
describe the
outcome(s) of the
assessment(s):**

Please provide the reference(s) if possible:

Please see responses to 2.1

See response to 2.1.1.

See response to 2.1.1

Regulatory decisions on the approval of hazardous substances and setting of management controls

The roadmap asserts the possibility of three approaches for regulating endocrine disruptors. It is unc

	<p>3.2. Have you conducted or are you aware of an assessment of the socio-economic impact of the 3 different options for regulatory approaches to decision making (option A-C) for substances identified as endocrine disruptors by any of</p>		
	No		
	No		
	Yes	In addition to comments	See response to 2.1.3.
	No		
	No		
	No		
under the HSNO Act are	No		
	No		
clear why the Commission	Yes	Please see question 3.2.	Please see question 3.2.
	No		
	No		

Please provide the reference(s) if

possible:

4.1. Please provide any other data or information that could help the Commission to conduct its impact assessment.

The extent and the way i

La suppression des subs

Science Policy Notice S
Science Policy Notice S
Desde el punto de vista c
CONSULTA PÚBLICA D
New Zealand (NZ) uses

Argentina comparte la pr

It is concerning, that with

**Please provide the
reference(s) if
possible:**

in which endocrine disrupting chemicals are regulated in Australia Agricultural and Veterinary Chemicals The

stances actives consid  r  es comme des perturbateurs endocriniens (en cas de mauvaise utilisation) aura   

PN2003-03, Assessing Exposure from Pesticides in Food - A Users Guide, provides an overview of Health
PN2003-03, Assessing Exposure from Pesticides in Food - A Users Guide, provides an overview of Health
de din  mica agroalimentaria y en el contexto de los tratados de libre comercio que ya est  n firmados y rati
A COMISS  O EUROPEIA SOBRE CR  TERIOS PARA IDENTIFICAR DESREGULADORES END  CRIN
a risk (rather than hazard)-based approach based on science, for determining whether substances with poi

reocupaci  n por los posibles efectos sobre la salud y el medio ambiente que las sustancias con propiedad

[a7431db3-da60-41c7-8a36-cd57ed851f9d/United States Submission Endocrine Disrupters 1-16-15.pdf](#)

the Australian Pesticides & Veterinary Medicines Authority (APVMA) regulates agricultural and veterinary chemicals

des impacts très grave sur l'économie de notre pays. Pratiquement toutes les substances actives de produits

Canada's approach to estimating risk and exposure from pesticide residues in food (see: <http://www.hc-sc.gc.ca/health/pesticides/food/index-eng.php>)
Canada's approach to estimating risk and exposure from pesticide residues in food (see: <http://www.hc-sc.gc.ca/health/pesticides/food/index-eng.php>)
ficados con la Unión Europea, el ICA tiene como misión, trabajar por la sanidad agropecuaria y la inocuidad
IOS1. Esta informação refere-se à consulta sobre a definição dos critérios de identificação dos desreguladores
tentially endocrine disrupting properties should be approved, in accordance with the WTO Agreements and

es de Disruptores Endocrinos (DE) podrían tener. Sin perjuicio de ello, cualquier decisión que sobre las reacciones

emicals (including plant protection products, veterinary medicines and veterinary chemical products such

uits phytosanitaires utilisés sur nos cultures de rente (café, cacao, hévéa, palmier à huile, coton, banane,..

sc.gc.ca/cps-spc/pubs/pest/_pol-guide/spn2003-03/index-eng.php). Further general information on Health
sc.gc.ca/cps-spc/pubs/pest/_pol-guide/spn2003-03/index-eng.php). Further general information on Health
dad en la producción primaria para proyectar los negocios del agro Colombiano al mundo, debe propend
adores endócrinos no contexto da aplicação do regulamento relativo aos produtos fitofarmacêuticos e de
id international standards and norms. NZ considers that basing such determinations on hazard identificat

ismas se adopte debe respetar los principios multilateralmente acordados, en particular las disposicione

as ectoparasitídeos). APVMA, in conjunction with the Australian Department of Health's Office of Chemi

..) seront frappées d'interdiction. Et pourtant il existe une gamme variée de ravageurs à combattre absolu

1 Canada's risk assessment and risk management approaches for pesticides may be found in Science Po
1 Canada's risk assessment and risk management approaches for pesticides may be found in Science Po
er por que las exportaciones de Colombia a Europa no se vean afectadas y por el contrario cumplan con
, regulamento relativo aos produtos biocidas, aberta entre 26.09.2014 e 16.01.2015.2. Para a avaliação d
ion and/or characterisation alone (as envisaged in the four options), without a robust risk-assessment me

s del Acuerdo sobre la Aplicación de las Medidas Sanitarias y Fitosanitarias (AMSF) y el Acuerdo sobre la

ical Safety (OCS) and the Australian Department of the Environment, independently evaluates the safety

iment sur ces plantes, afin d'avoir des niveaux de productions satisfaisants.Nous pensons que le danger

olicy Notice SPN2000-01, A Decision Framework for Risk Assessment and Risk Management at the Pes
olicy Notice SPN2000-01, A Decision Framework for Risk Assessment and Risk Management at the Pes
i los requisitos fitosanitarios exigidos para la importación, desde este punto de vista el ICA como respons
do documento intitulado Defining criteria for identifying Endocrine Disruptors in the context of the impleme
thodology, lacks scientific justification. Consequently, NZ does not support any of the four options. Given

os Obstáculos Técnicos al Comercio de la OMC, particularmente: (i) no crear obstáculos innecesarios al

and performance of pesticides and veterinary medicines intended for sale, ensuring that the health and s

existe, certes; mais les risques (danger*exposition) pourraient être minimisés par la mise en oeuvre des b

t Management Regulatory Agency (see: http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/spn2000-C
t Management Regulatory Agency (see: http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/spn2000-C
able de la Sanidad e Inocuidad Agropecuaria debe facilitar a lo agricultores las herramientas (Agroinsum
entation of the Plant Protection ProductRegulation and Biocidal Products Regulation, apresentam-se os c
the limited information provided and lack of clarity around how the options, if adopted, would be impleme

comercio, (ii) no restringir el comercio más de lo necesario para proteger la salud o para alcanzar los obj

safety of people, animals, crops and the environment are protected. Product efficacy and impacts on inter

bonnes pratiques d'utilisation des pesticides.

01/index-eng.php). Other statutes/risk assessment programmes of Health Canada have a similar risk-bas
01/index-eng.php). Other statutes/risk assessment programmes of Health Canada have a similar risk-bas
os), necesarias para garantizar la calidad de sus productos, libre de patógenos, plagas y además de las
comentários a seguir:Campo C - Quanto ao Aspecto I: Critérios da EU para identificação de DE:Identifica
nted, it is difficult to assess the potential impact on trade. However, for an exporting country like NZ, this

jetivos legítimos tutelados, y (iii) que los riesgos se evalúen teniendo en consideración la información cier

national trade are also factors which must be considered for most of the products the APVMA assesses. .

ed approach.

ed approach. This submission presents Health Canada's input from a regulatory science perspective. For calidades organolépticas y nutricional.El ICA como autoridad nacional competente y responsable de la fiti-se, como a mais apropriada, a Opção 4 - WHO/IPCS definition to identify endocrine disruptors and inclu could be significant. Accordingly, NZ encourages the EU to notify any draft regulations to the WTO SPS

ntífica/técnica existente, así como las normas internacionales pertinentes.Es fundamental que los miembr

APVMA's guidelines on mammalian toxicology data submission can be found at <http://apvma.gov.au/node>

comprehensive Government of Canada input, including trade perspective, please note submission by C
tosanidad garantizara en la producción primaria el uso eficiente y responsable de las mencionadas herram
sion of potency as element of hazard characterization (hazard identification and characterisation). Trata-se
and TBT Committees to enable trading partners to consider the specific implications and provide comme

ros de la OMC al elaborar, adoptar o aplicar cualquier medida, opten por aquella menos restrictiva del co

3/1036#Data_elements_and_guidelines. While they do not make spe

iris Leggett, Counsellor (Agriculture) , Mission of Canada to the European Union.
mientas.Teniendo en cuenta que gran parte de las exportaciones d
e de uma definição de critérios para DE da Organização Mundial da Saúde (OMS), com a adi
ents. All hazardous chemicals and chemical products

mercio haciendo que sean proporcionales a los objetivo

