



Nutritional and Herbal Practitioners: Growing Your Business In Spite Of Stringent EU Laws

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European Commission

“...the Directorate General Health and Consumer Protection would like to emphasize that the main aim of the food supplements Directive is to ensure that food supplements placed on the market are safe and provide a wide choice to consumers to supplement their diet.

Moreover, it is important to note that food supplements are regulated as food and are **intended for supplementing the normal diet rather than having therapeutic effects**. In fact, claims as to treatment, cure or prevention of disease would not be allowed for food supplements and would place the product under the legal framework of medicines.

Your key exposure points

- **Questionnaire & consultation:**
risk of medical diagnosis
- **Oral treatment recommendations/ protocols:**
Medicinal claims and unapproved health claims
- **Written recommendations/protocols:**
Medicinal claims, use of unregistered medicines or unauthorised novel foods
- **Marketing promotional materials, websites, etc.:** non-allowed health claims and medicinal claims



Challenges - general

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1

Harmonisation



Challenges - general

1

Harmonisation



2

Effectiveness
/ safety



Challenges - specific (regulatory)

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1 Ingredients

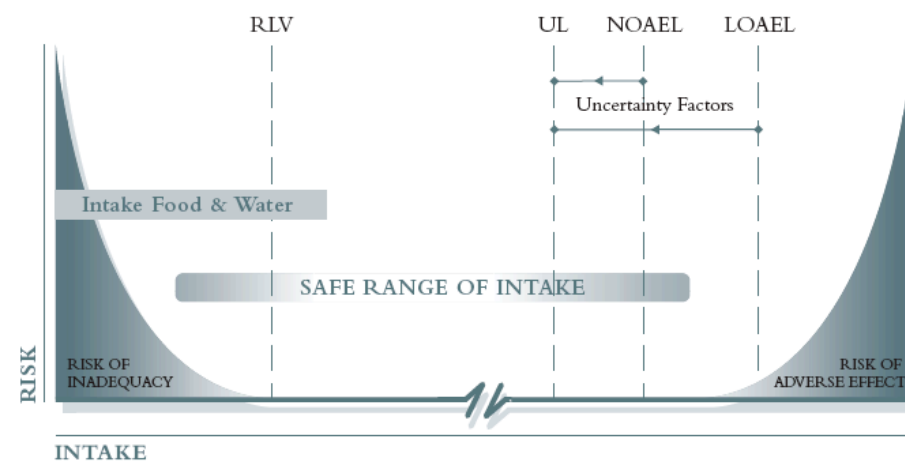


Challenges - specific (regulatory)

1 Ingredients



2 Doses

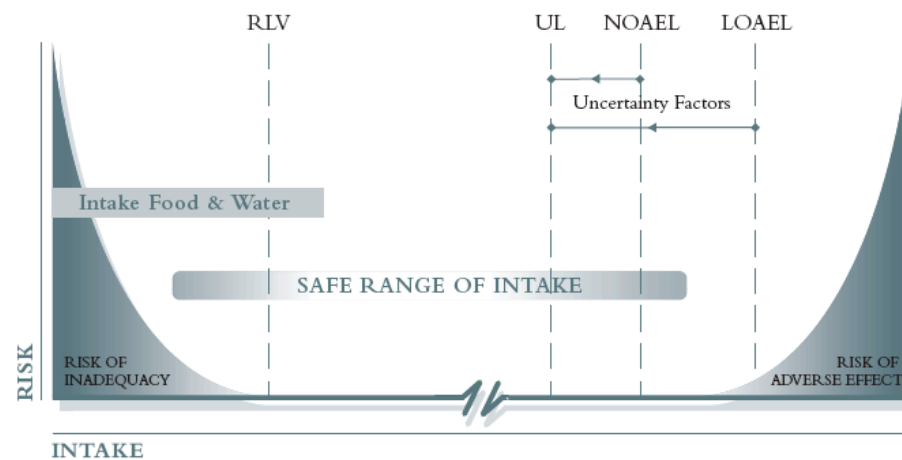


Challenges - specific (regulatory)

1 Ingredients



2 Doses



3 Claims

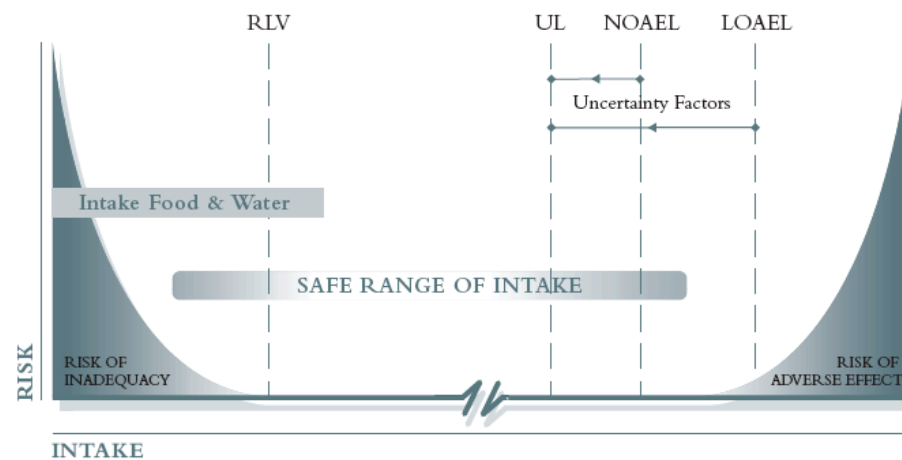


Challenges - specific (regulatory)

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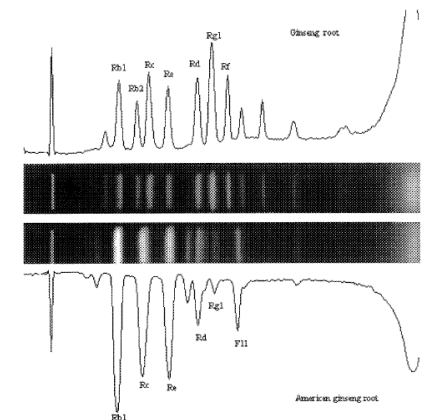
2 Doses



3 Claims



4 QC

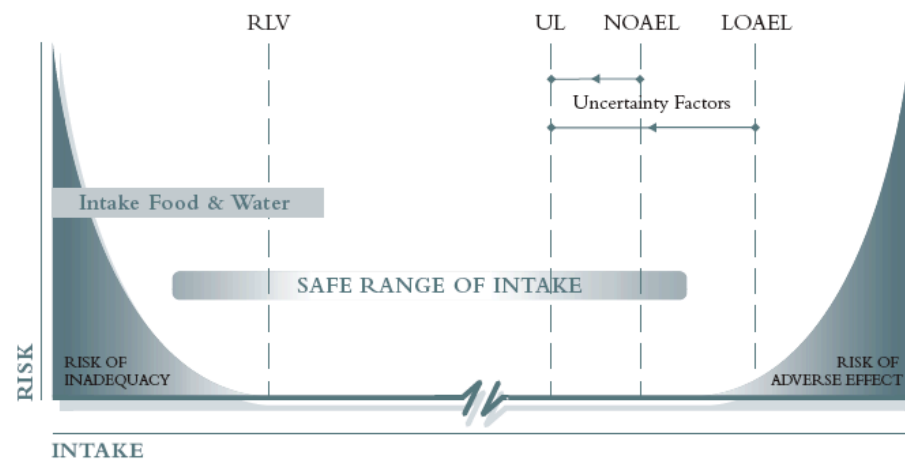


Challenges - specific (regulatory)

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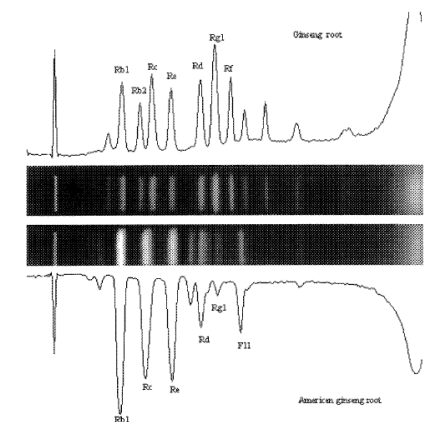
2 Doses



3 Claims

4 QC

= science and law



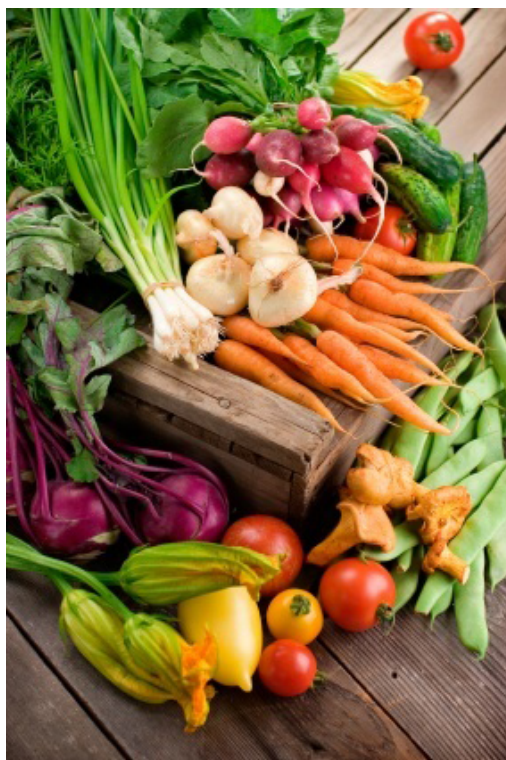
Regulatory challenges: *products*

FOOD

DRUG



unauthorised
NOVEL FOOD



Regulatory challenges: *products*

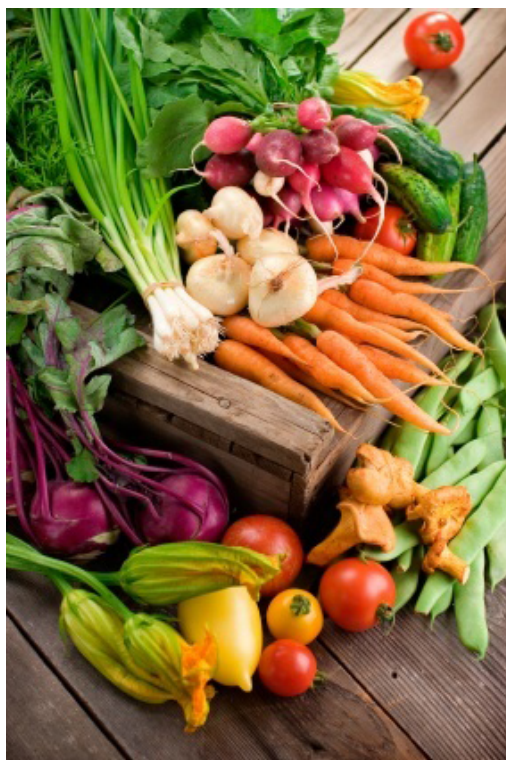
borderline

FOOD

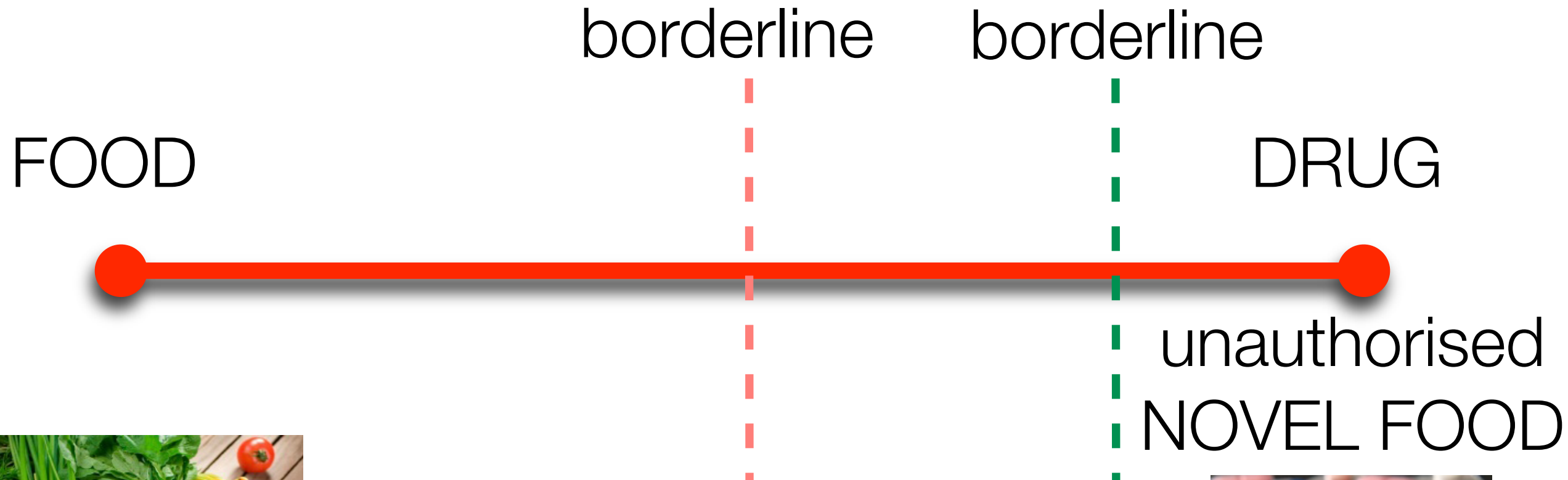
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unauthorised
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Regulatory challenges: *products*



Regulatory challenges: *products*

borderline borderline borderline

FOOD

DRUG



unauthorised
NOVEL FOOD



Regulatory challenges: *claims*

ALLOWED or
AUTHORISED
CLAIM

UNAUTHORISED
CLAIM



Regulatory challenges: *claims*

ALLOWED or
AUTHORISED
CLAIM

borderline

UNAUTHORISED
CLAIM



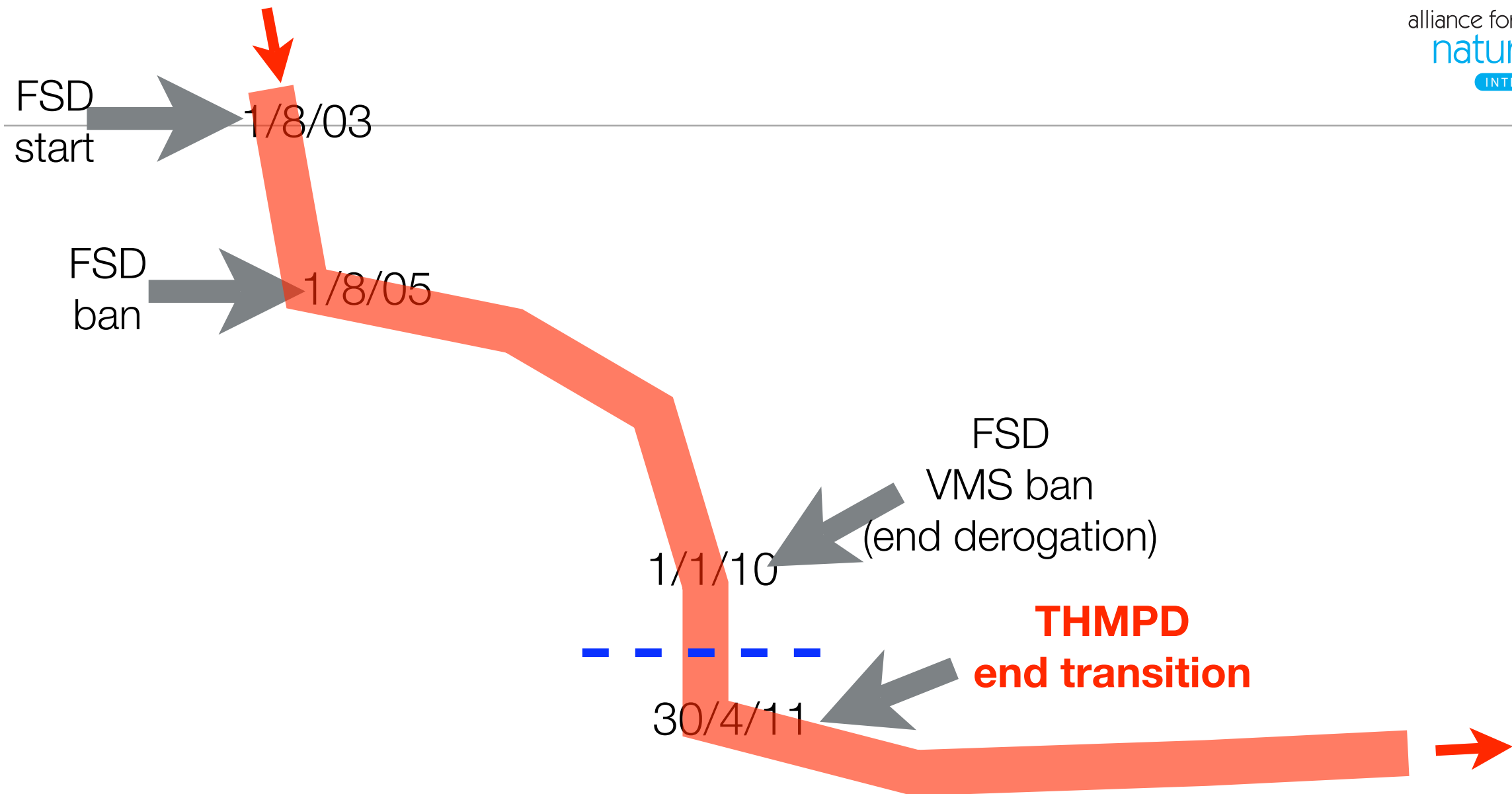
Harmonisation vs consumer protection?



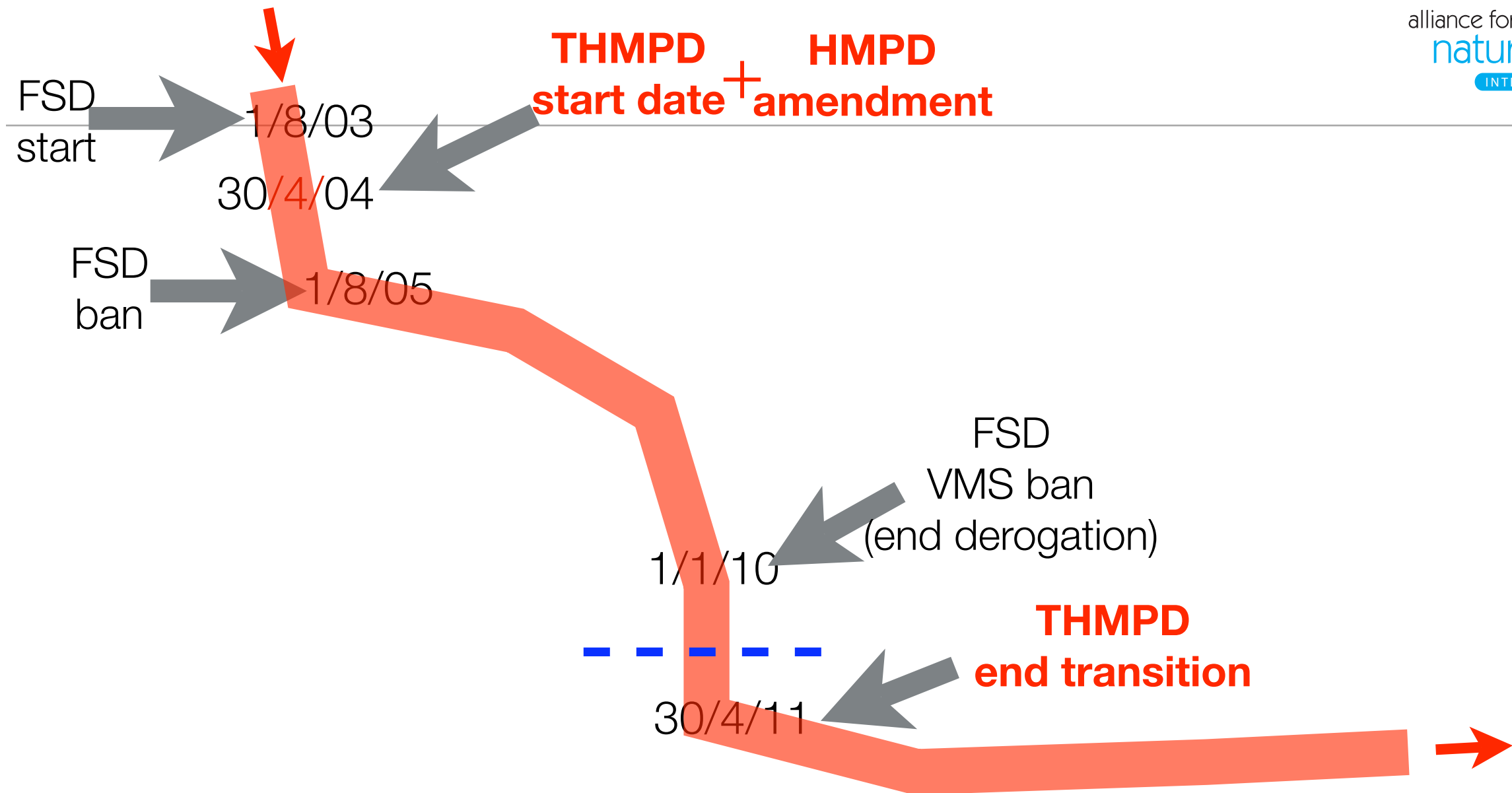
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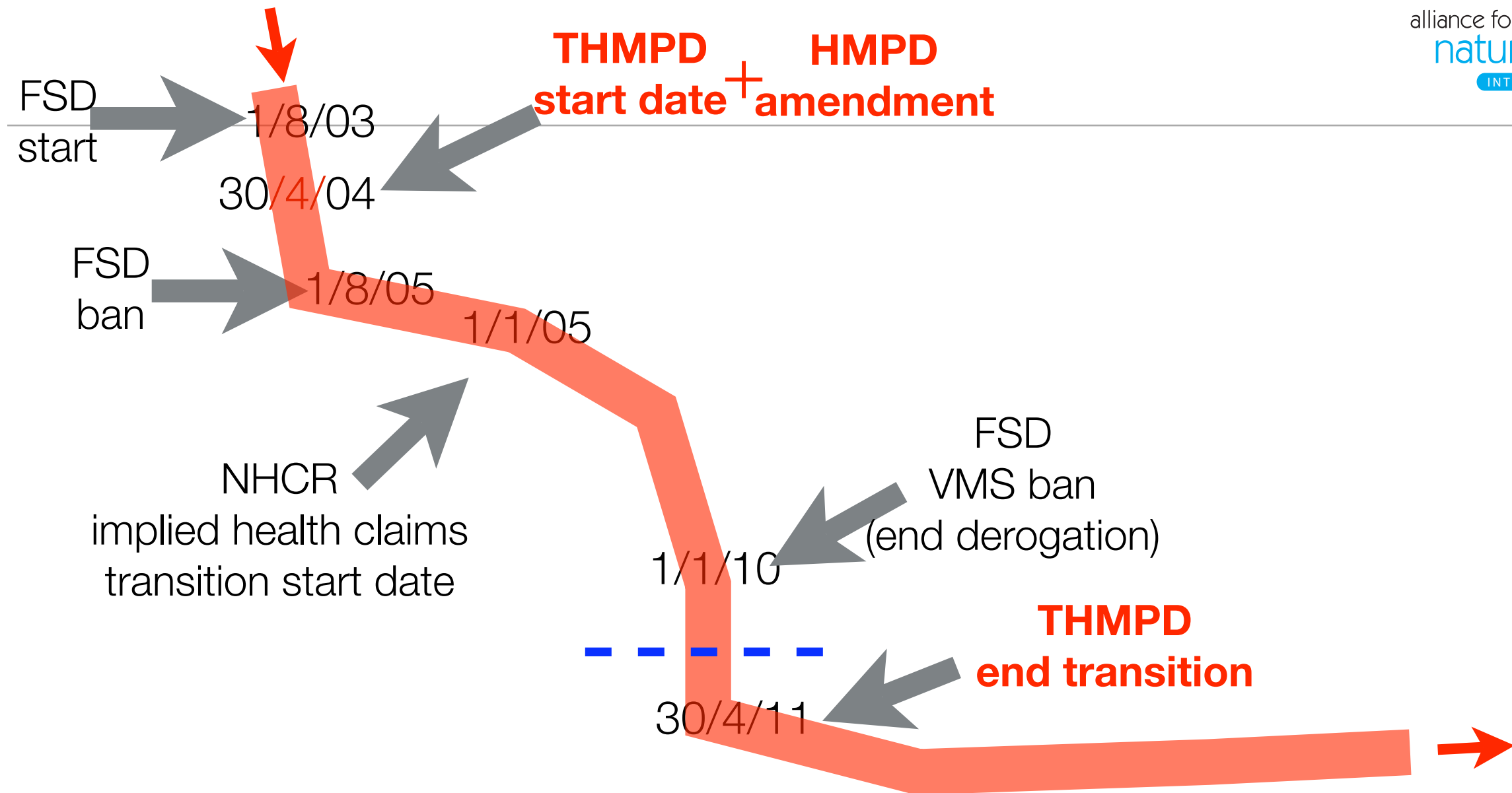
Gradualism in the EU ...



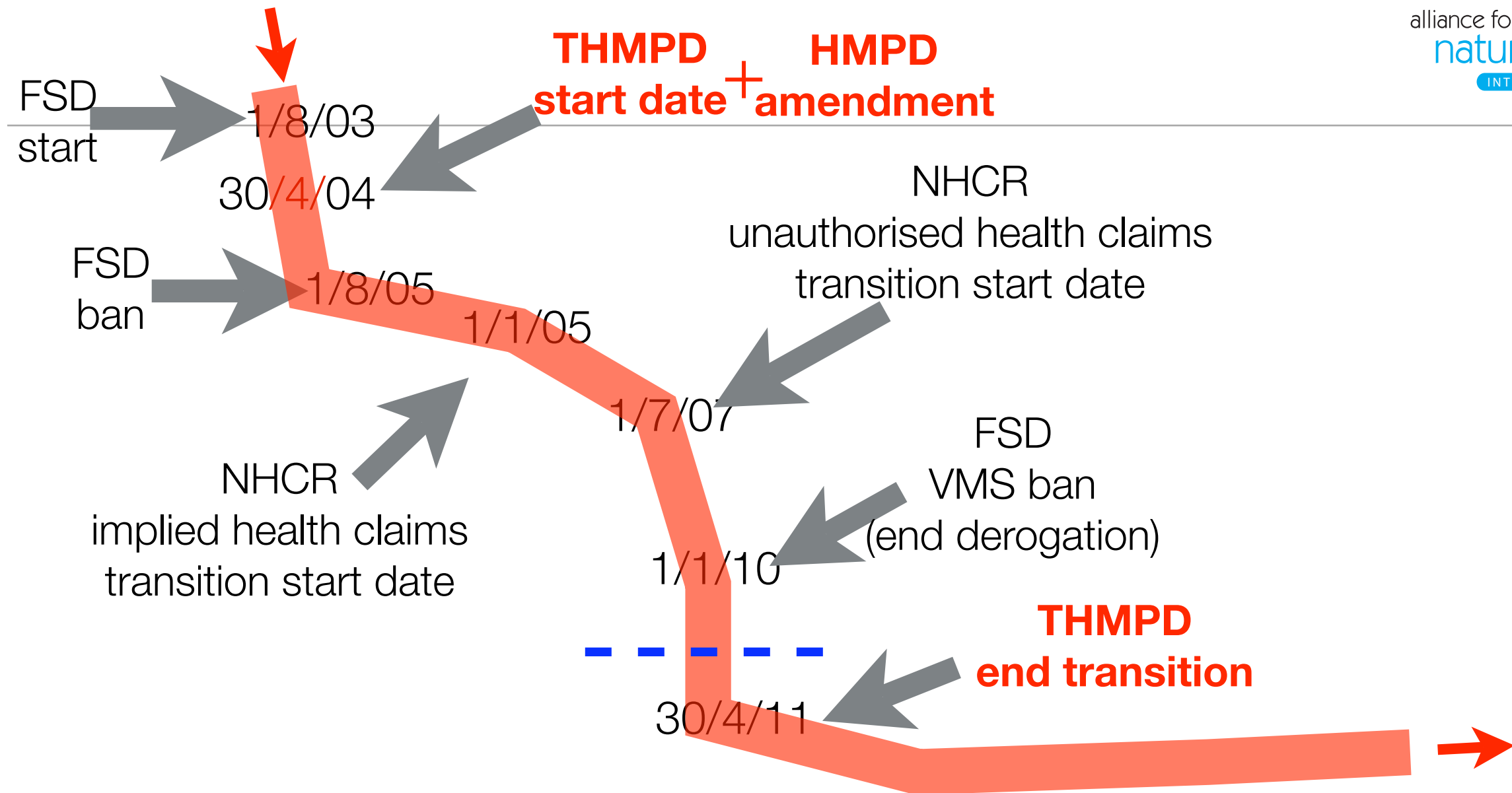
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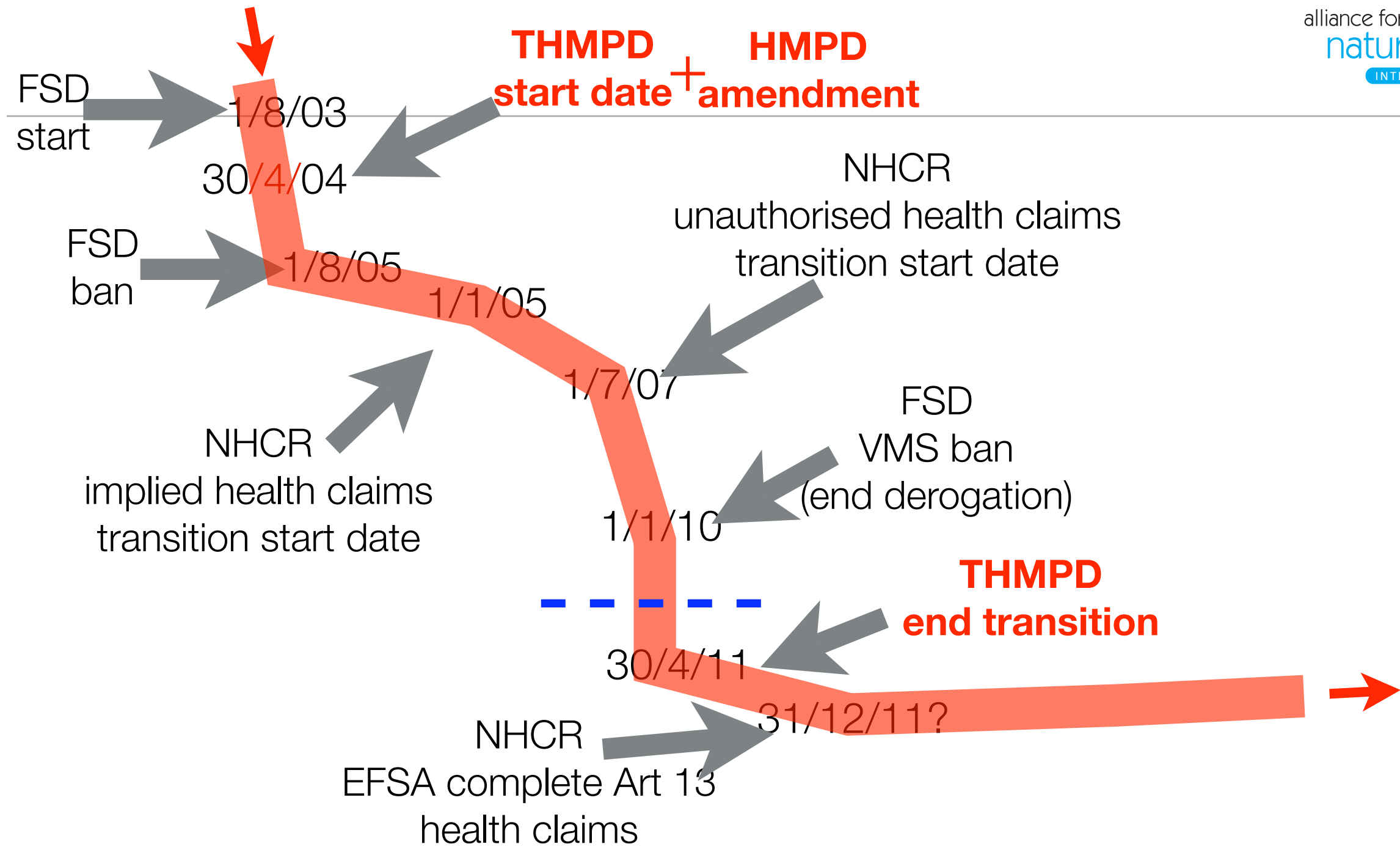
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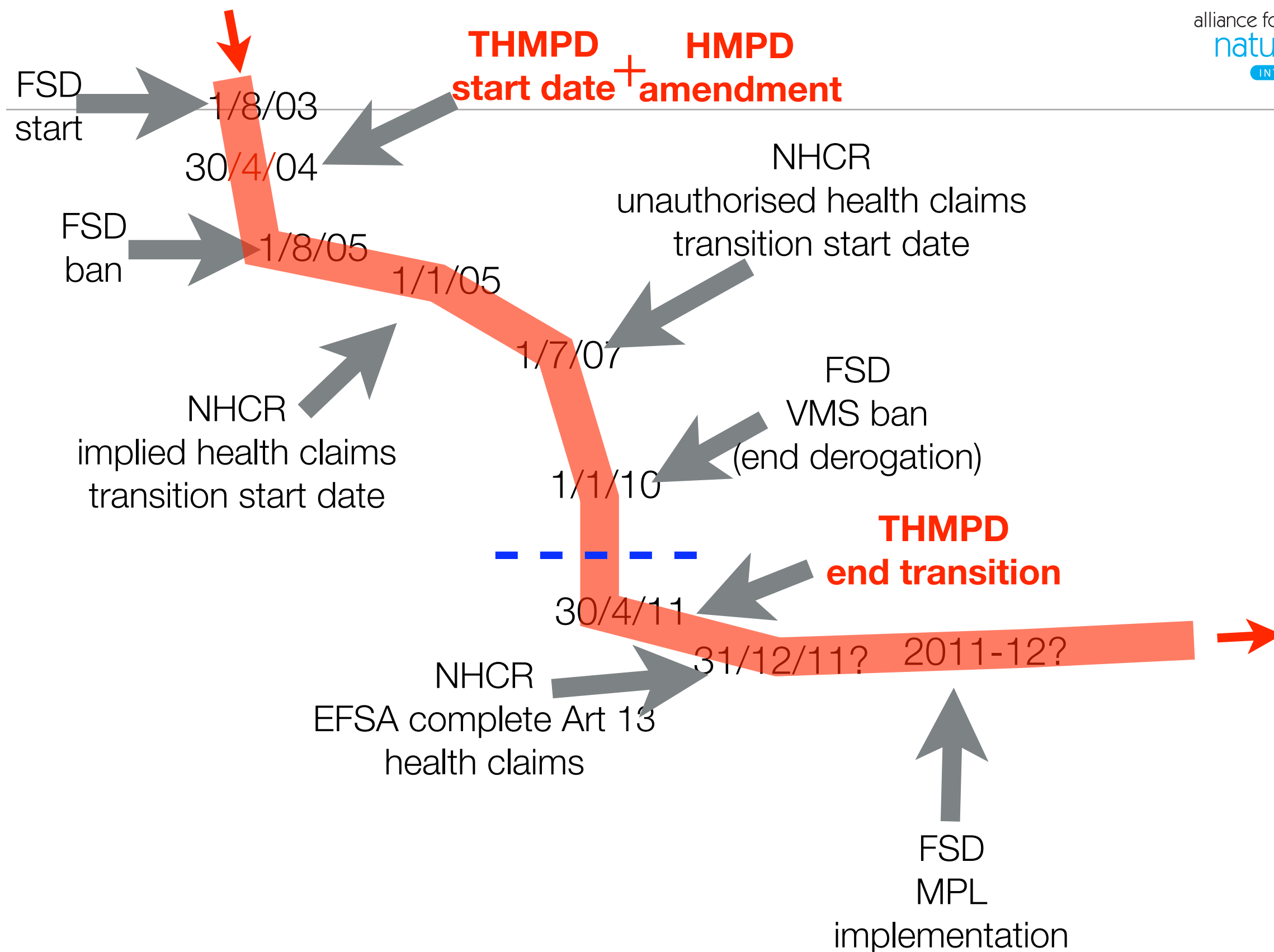
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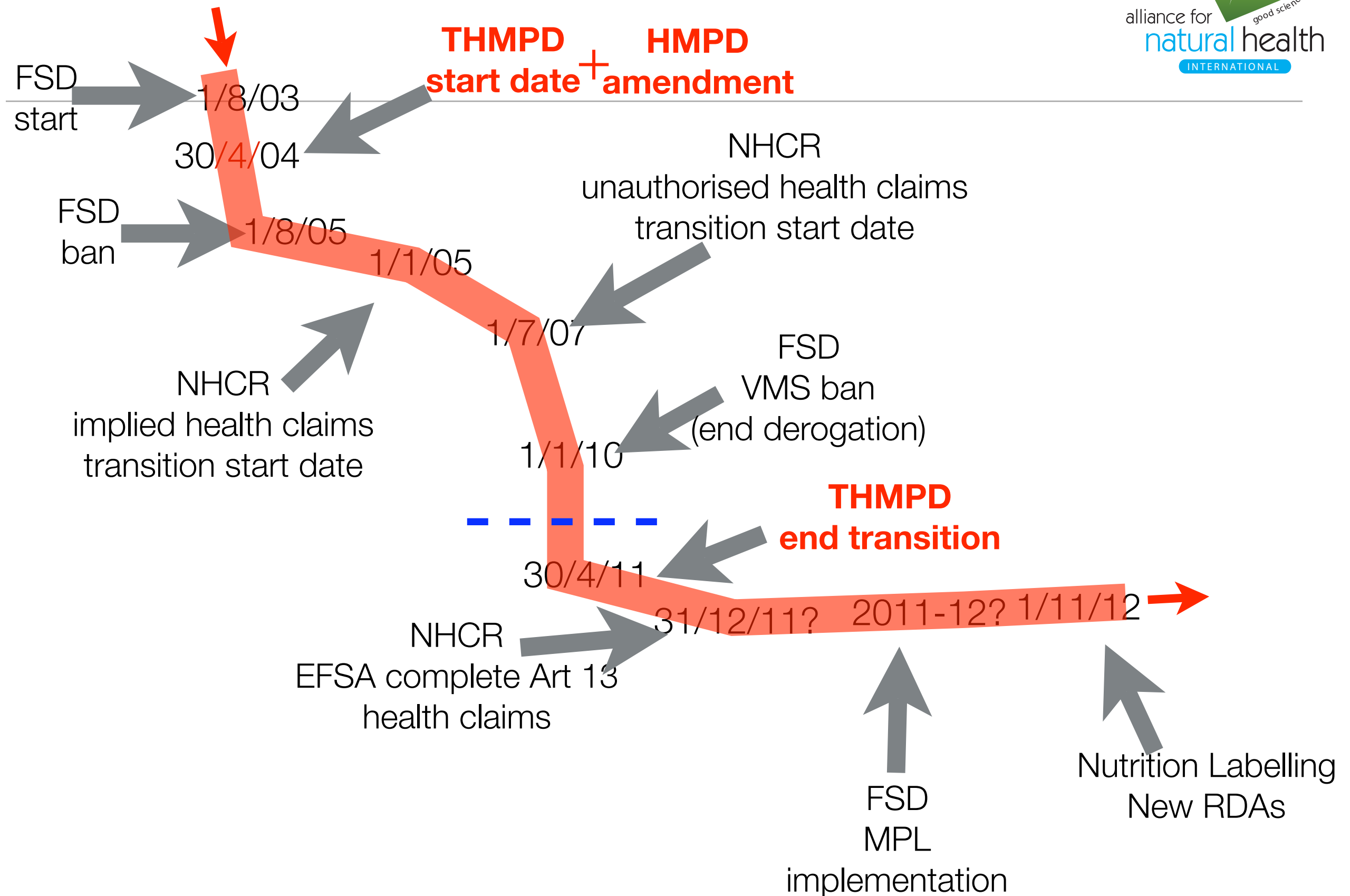
Gradualism in the EU ...



Gradualism in the EU ...




Gradualism in the EU ...



The EU food-medicine borderline




The EU food-medicine borderline




Food

Conventional
and functional,
including botanicals
(not dose forms)



**Medicinal
Products**

Registered



Mag
prescrip

The EU food-medicine borderline

Food
Conventional
and functional,
including botanicals
(not dose forms)

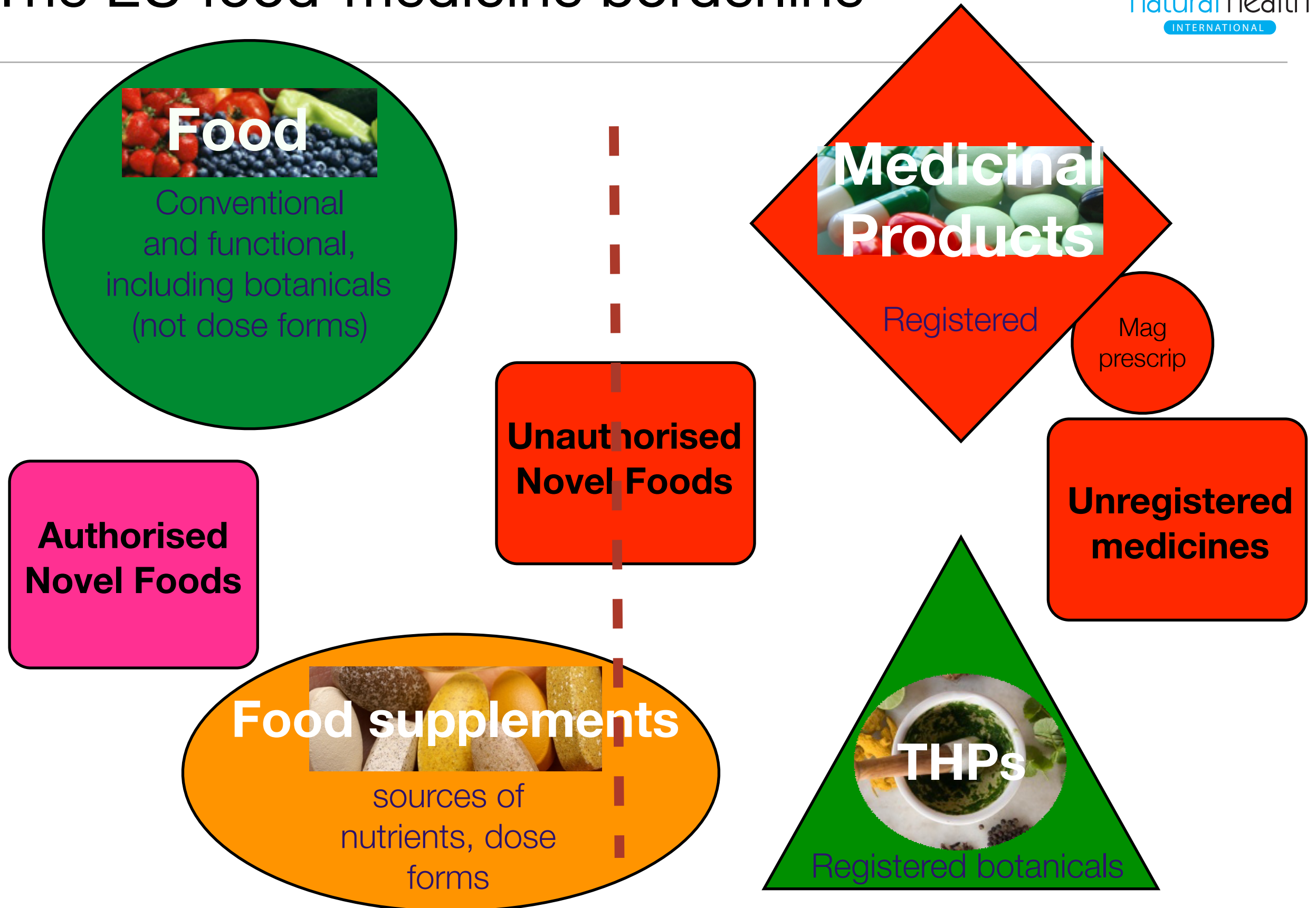
Food supplements
sources of
nutrients, dose
forms

Medicinal Products
Registered

Mag
prescrip

THPs
Registered botanicals

The EU food-medicine borderline



Which products can become drugs?



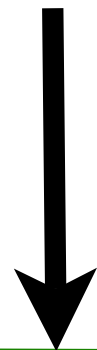
Which products can become drugs?



↑
Whole
foods, dried
foods, no
medicinal
claims

Which products can become drugs?

Herbs with history
of food use (whole,
aqueous extracts,
low dosage)



FOOD



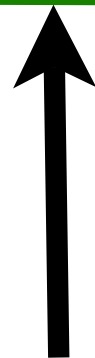
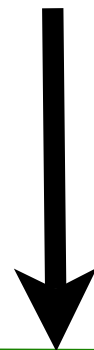
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DRUG

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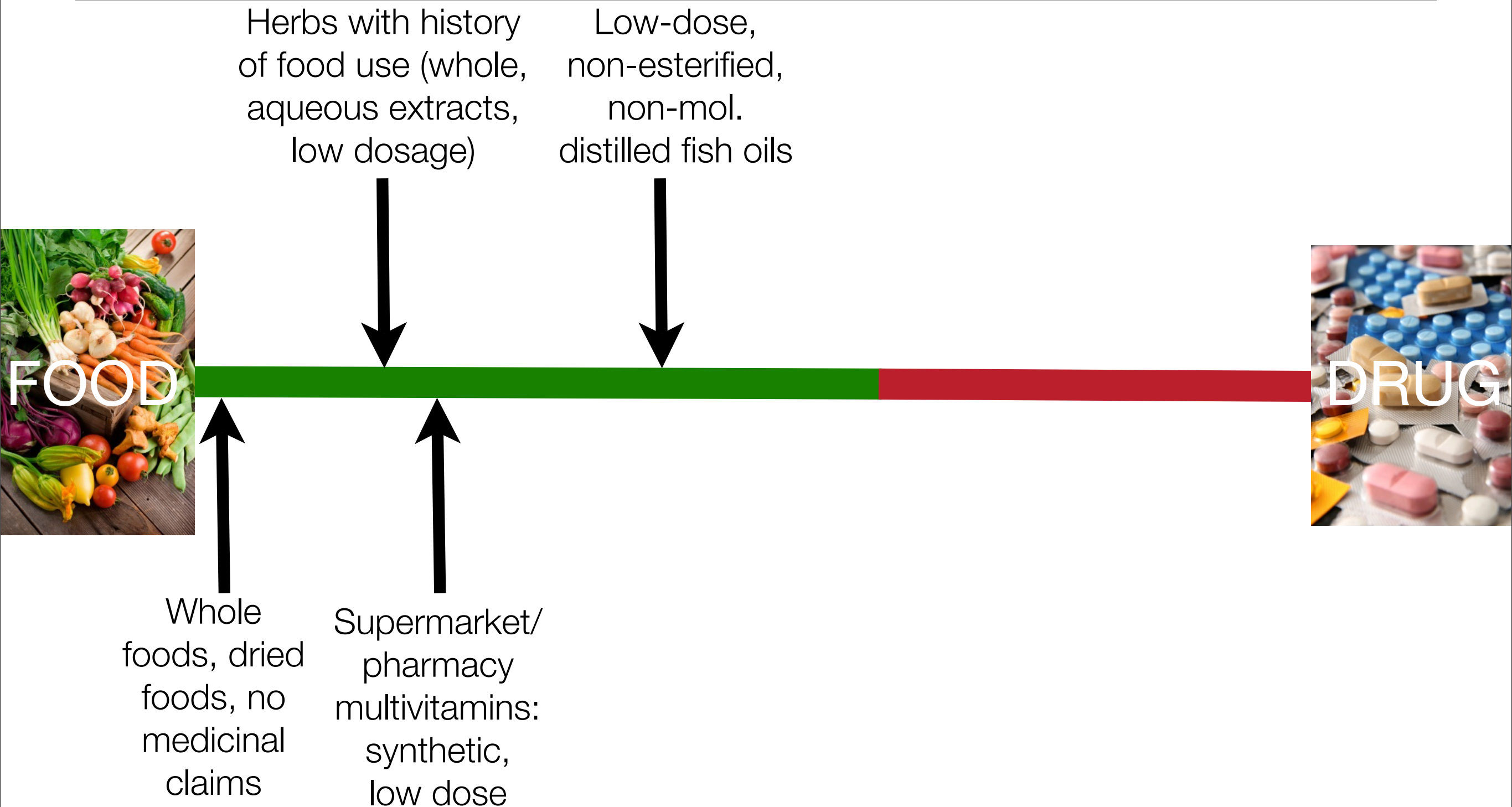
Herbs with history
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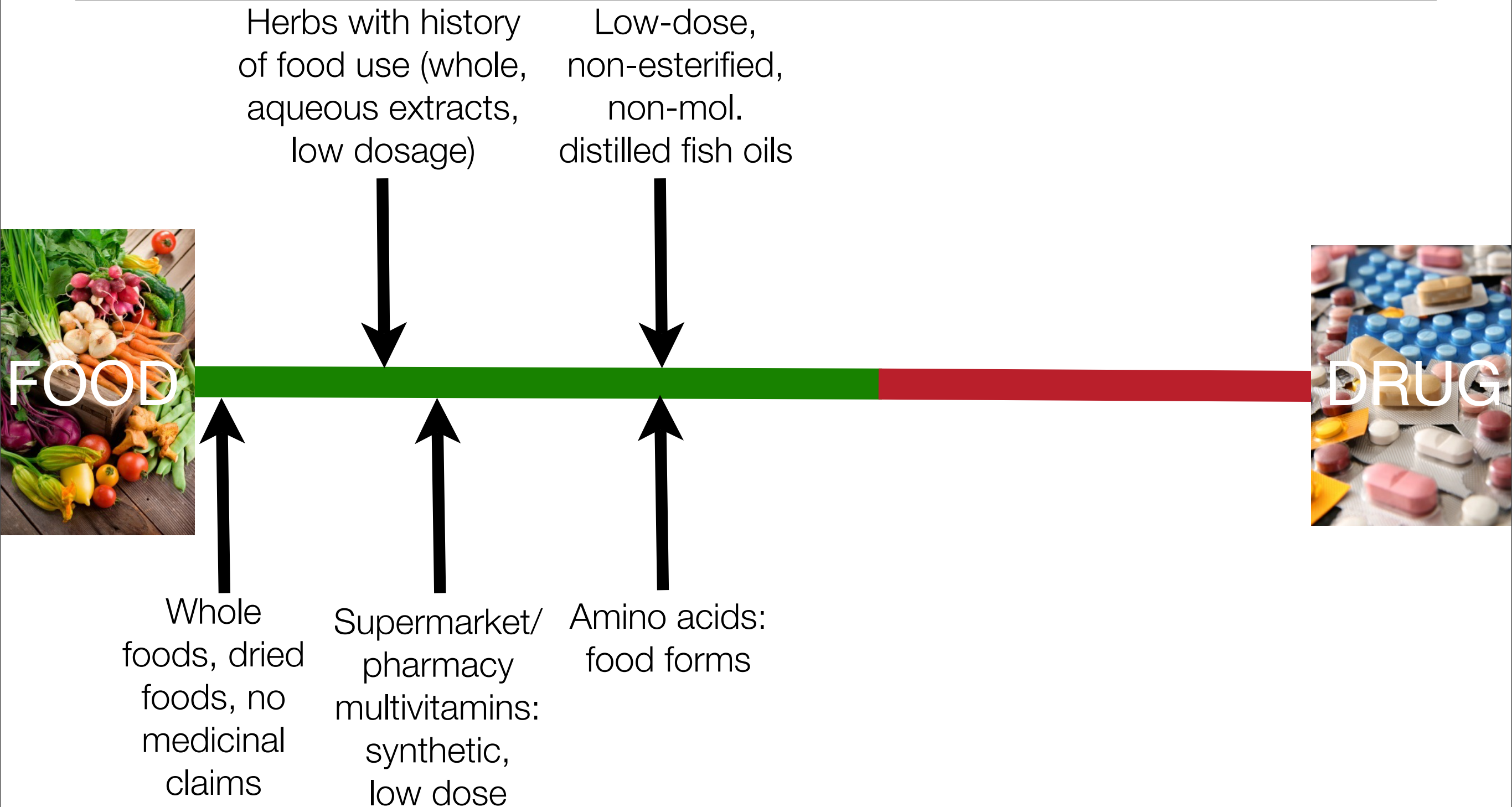
Whole
foods, dried
foods, no
medicinal
claims

Supermarket/
pharmacy
multivitamins:
synthetic,
low dose

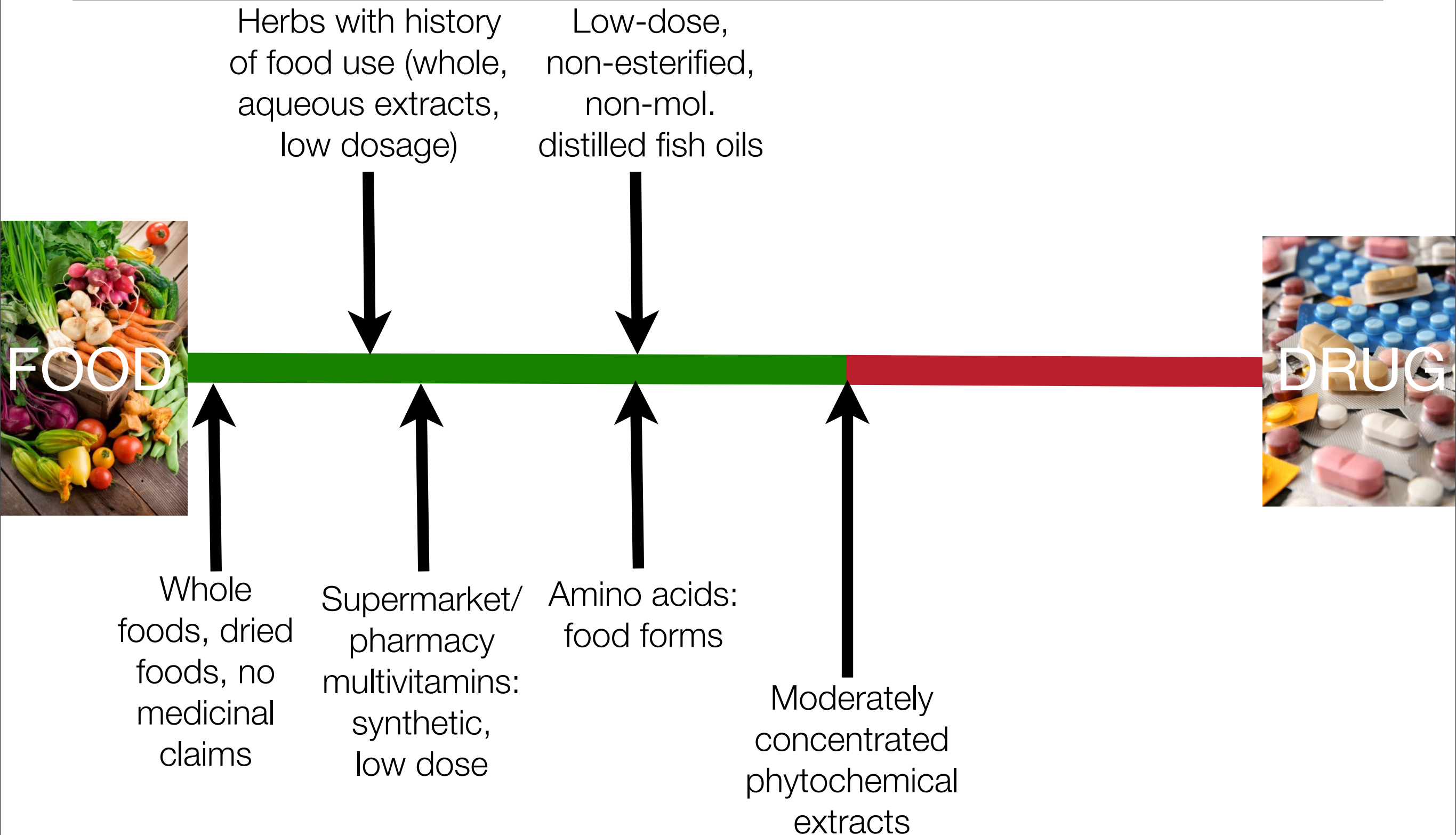
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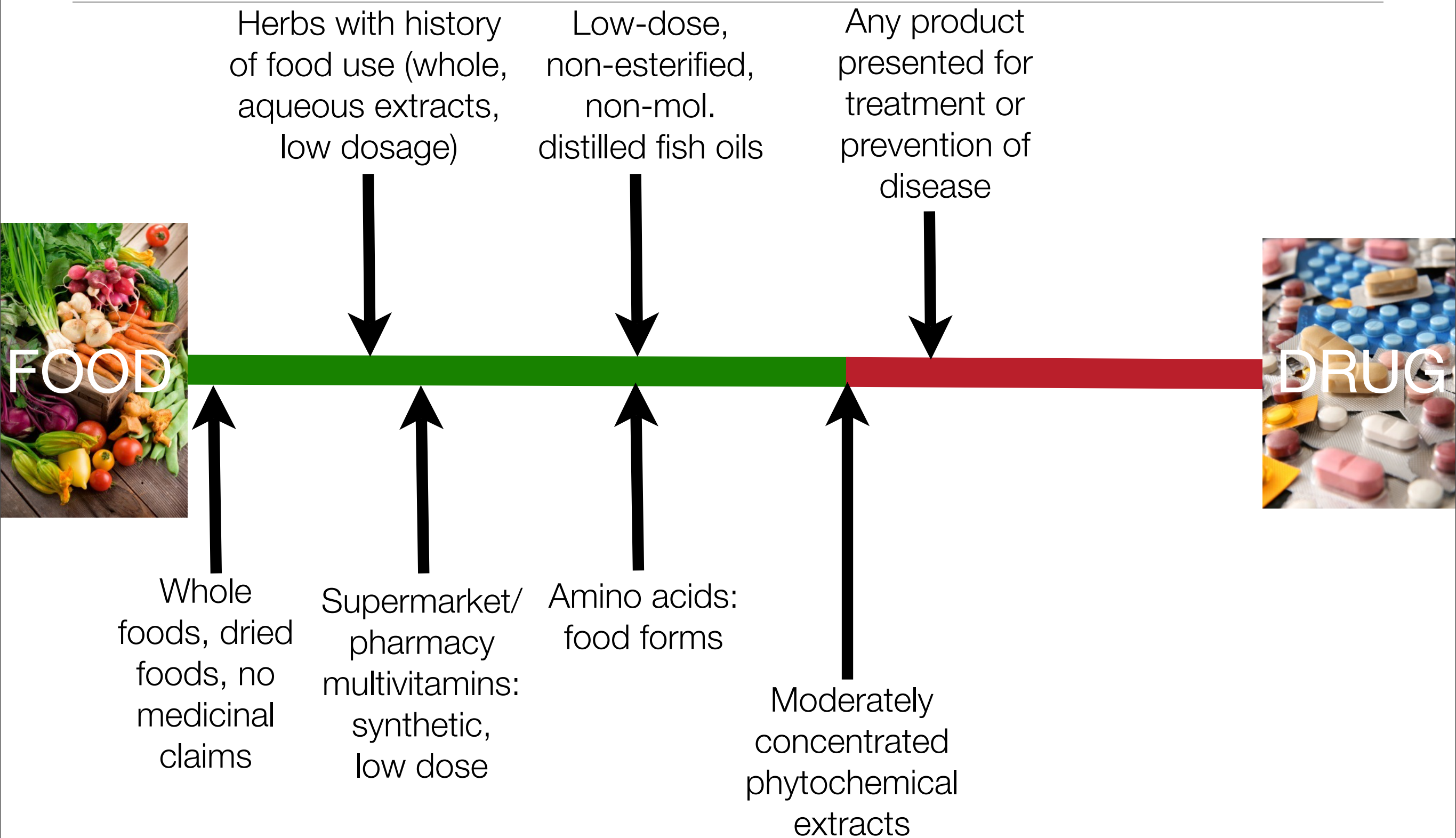
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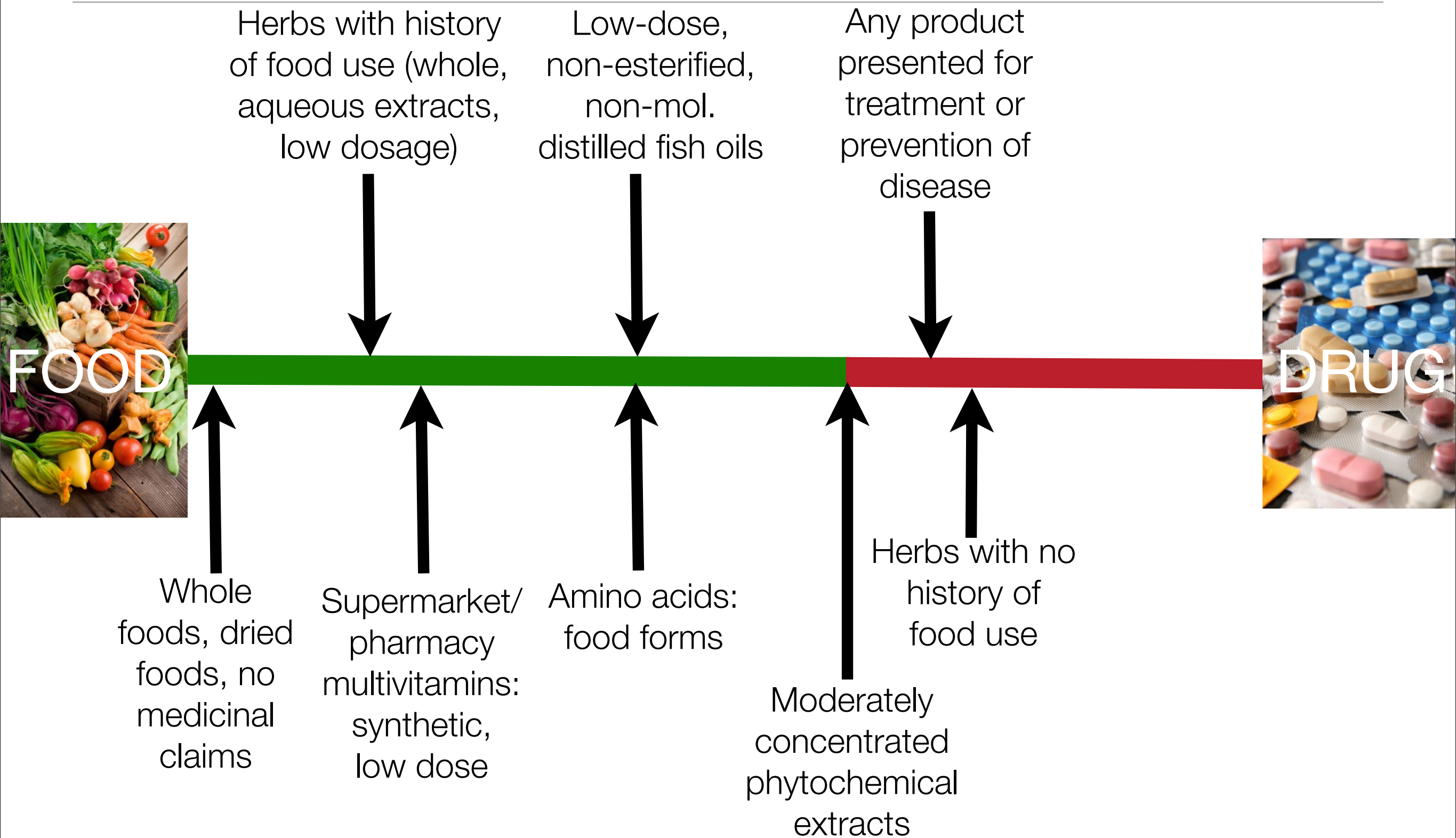
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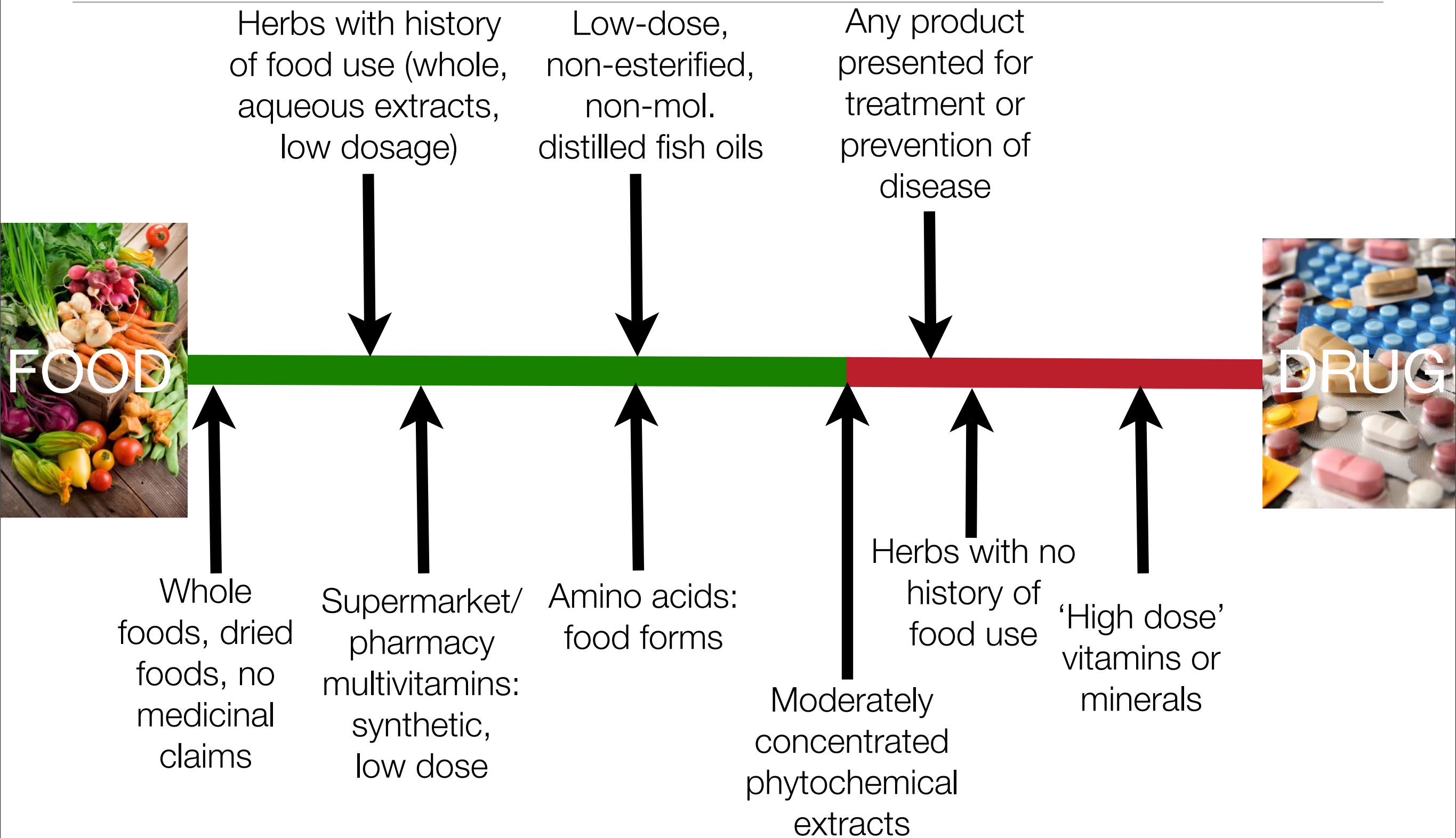
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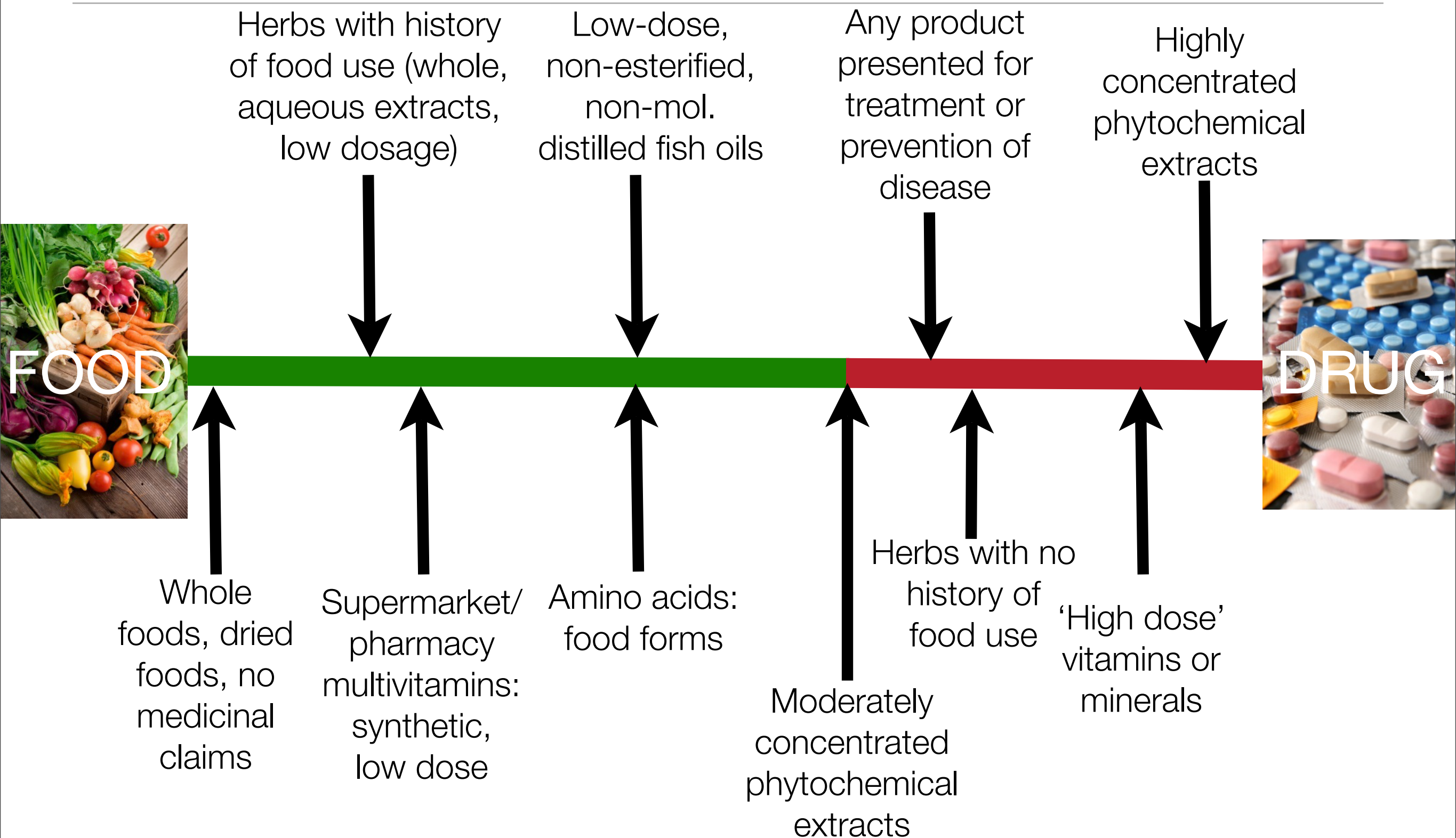
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Which products can become drugs?



Herbal dilemma: the world of medicines exemptions, statutory regulation and 'specials'

Medicines Act (1968)

S 12(1) "herbalists' exemption" - one-to-one

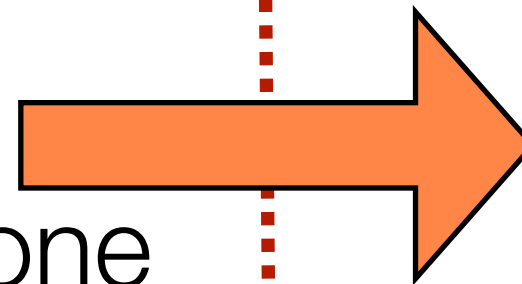
S 12(2) product exemptions

Herbal dilemma: the world of medicines exemptions, statutory regulation and 'specials'

April 2011

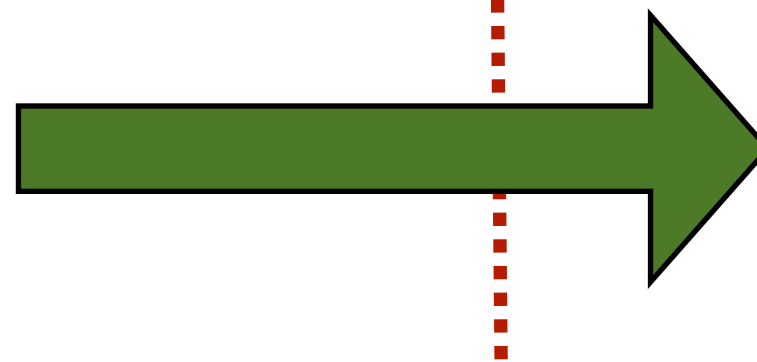
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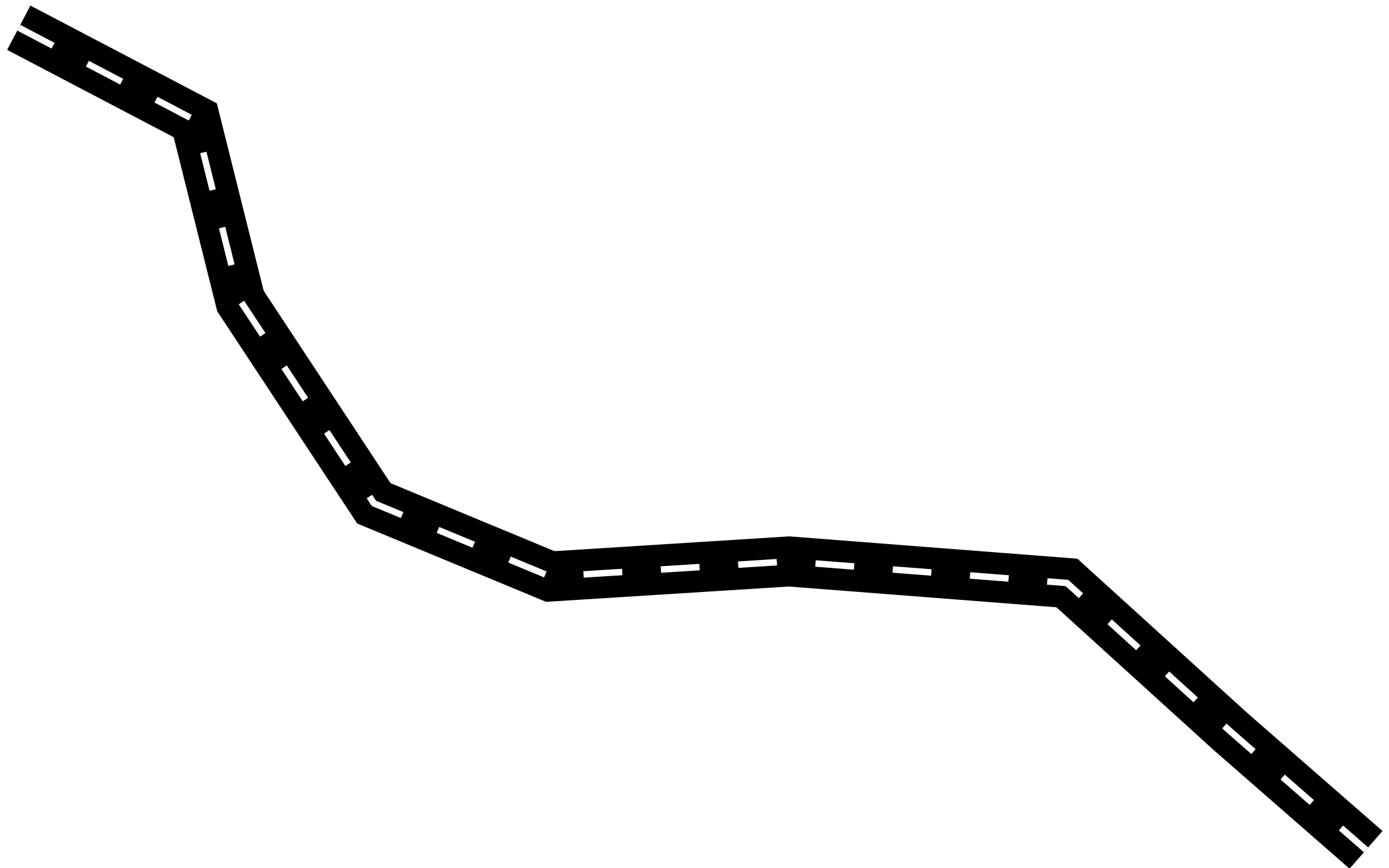
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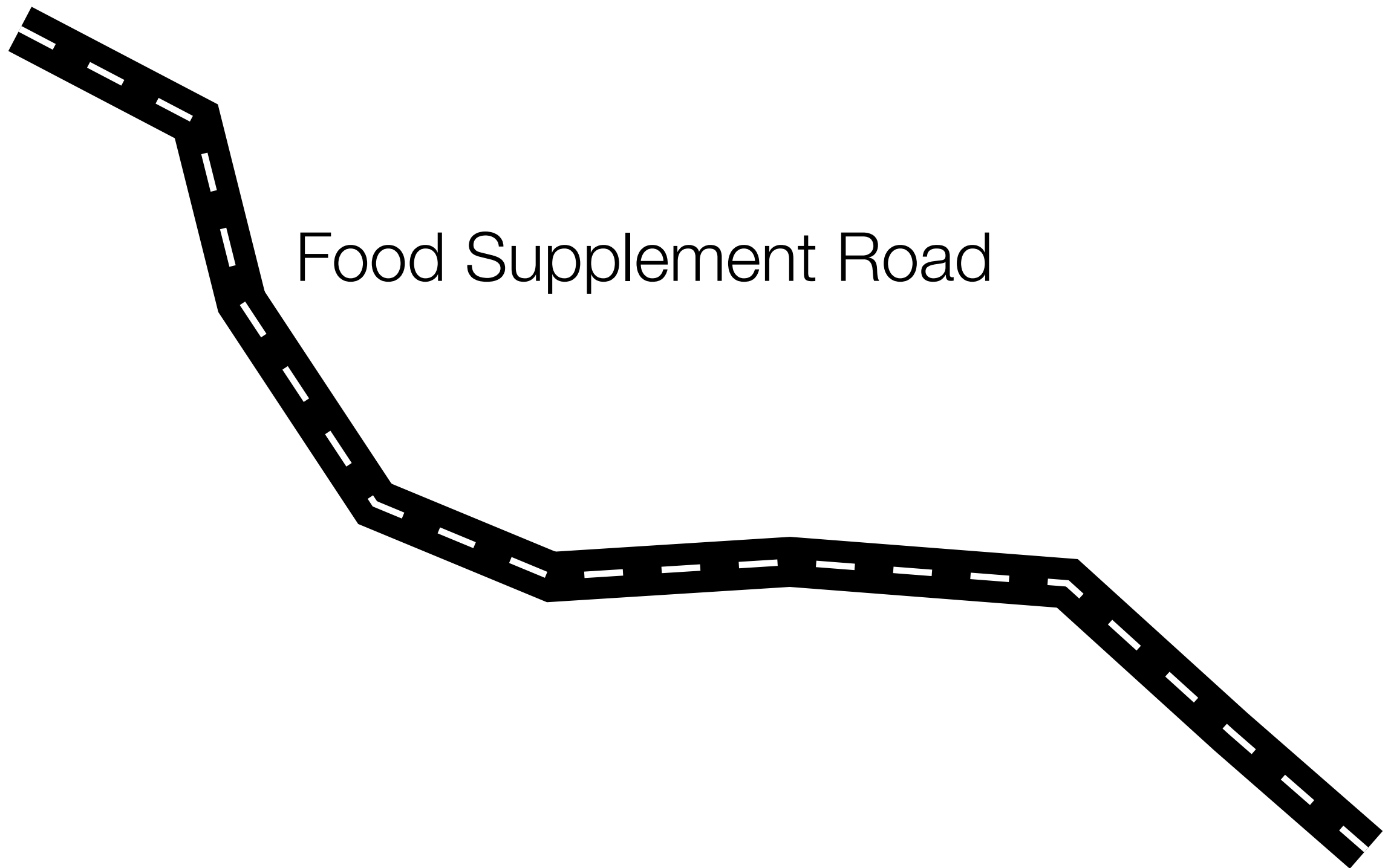
THMPD

What's the problem for many herbals?

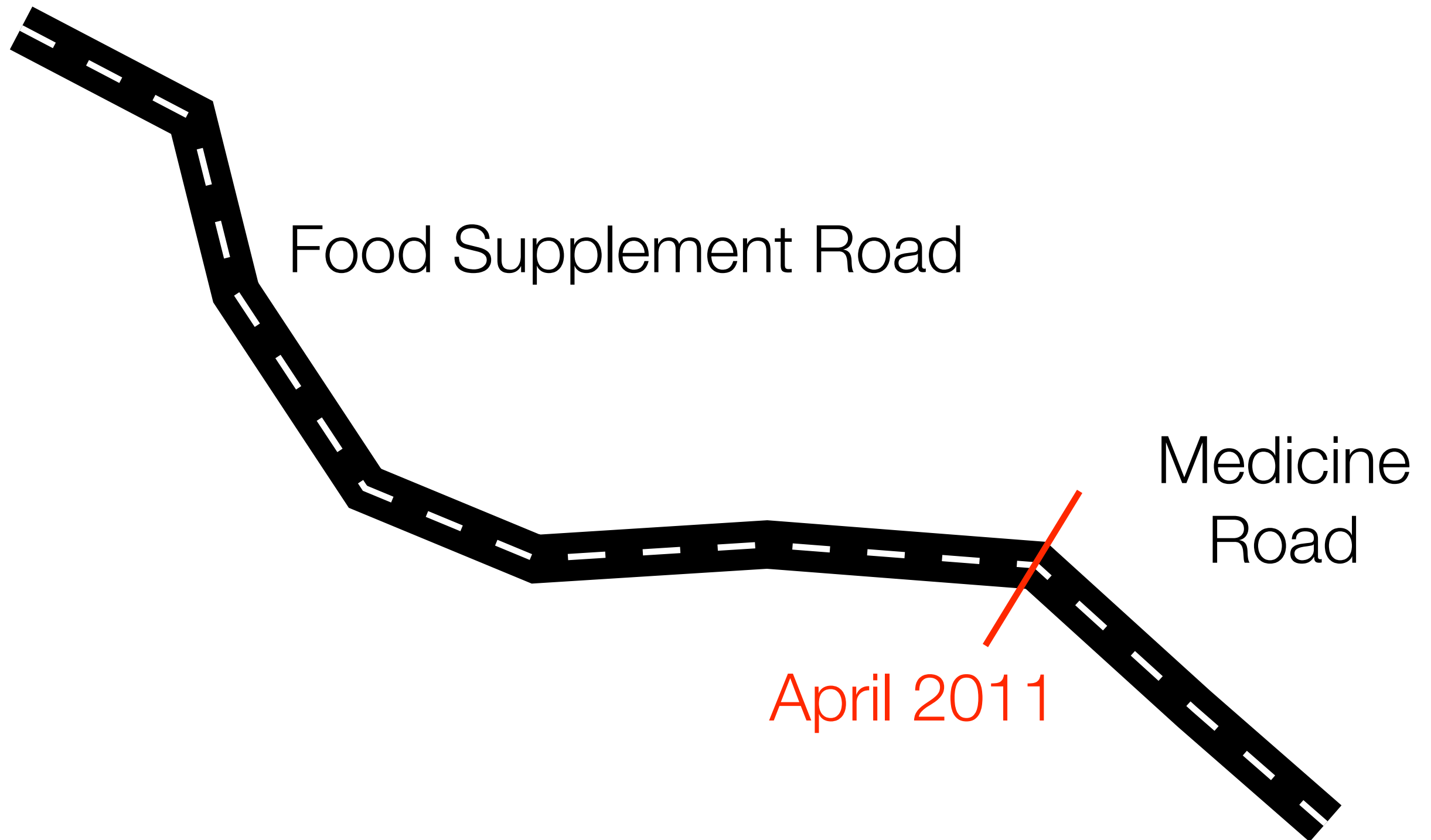
What's the problem for many herbals?



What's the problem for many herbals?



What's the problem for many herbals?



Major challenges of THMPD

- '30-year rule'; 15 year EU usage
- Pharmaceutical standards (including stability and genotoxicity testing) derived from allopathic models
- Stability testing for complex formulae
- Not intended for use by practitioners
- Claims limited e.g. minor ailments only
- Non-herbal ingredients excluded
- Innovative combinations
- Cost per registration



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disproportionate, non-transparent and discriminatory

How can you help?

FORWARD WIDELY



http://www.anh-europe.org/campaigns/protect-traditional-medicinal-cultures#THMPD_video

How can you help?



YOUR PROFESSION NEEDS YOU!

warning:
many herbs will soon be illegal!
unless you act now

FUNDS are urgently needed for legal challenge to EU herb law!

- On 1st April 2011, the EU's Traditional Herbal Medicinal Products Directive (THMPD) comes fully into force
- After this date, many of the herbal products you are currently using will effectively become ILLEGAL
- A legal challenge is urgently needed to change the faulty text in the Directive. Our expert lawyers indicate the grounds for challenge are strong...
- YOUR HELP is urgently needed!

Does the judicial review of the THMPD affect me?

The answer is "Yes" if you are in any way reliant on using products with herbal ingredients in your practice!



Our expertise is at your disposal for **FREE**, but we are asking practitioners to donate £20 per month for 6 months to help fund only the direct legal costs of the first stage – not much to keep your profession alive!

It's so simple to set up a regular donation at anh-europe.org – just click on the DONATE TODAY button and mark it 'Herb Challenge'.

Contact us now on:

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TOGETHER WE CAN SAFEGUARD YOUR PROFESSION

**COMMIT
YOURSELF
AND DONATE!**

**FORWARD TO
YOUR
COLLEAGUES**

Take home points

- Don't offer any diagnoses (except to yourself!)
- Don't associate commercial products with modifying, correcting, restoring health
- Check legality of products recommended
- Consider NHCR when making health claims of commercial products
- Keep commercial product recommendations separate from medical history and protocol (which can be generic)
- Avoid any medicinal claims and unauthorised health claims on any websites, marketing material, etc.



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- Support Base

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International Health News: CMO calls on Food and Drug Division to scrutinise herb...

Welcome to the Alliance for Natural Health

View Edit

Human health is suffering worldwide. The primary cause? Disconnection from nature and all things natural. The ANH is working to reconnect us. Play your part in the international campaign to regain and maintain our health naturally. Find out more... Also see our Mission Statement and the Message from the Executive Director.

- Choice
- Codex
- Trad Meds
- GM-free
- Sustain
- View all

OUR CAMPAIGNS
Health Choice
Your demand for natural health hurts the drug companies. Governments and some of the most powerful businesses in the world have responded by tying up the natural health sector in regulatory knots, in the hope of killing it off. Help us to help you.

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<http://bit.ly/cXGeuS>

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