

Health Claims Is it Working?

Nigel Baldwin
Director of Scientific & Regulatory
Consulting, Europe
nbaldwin@cantox.com
+44 1252 400505

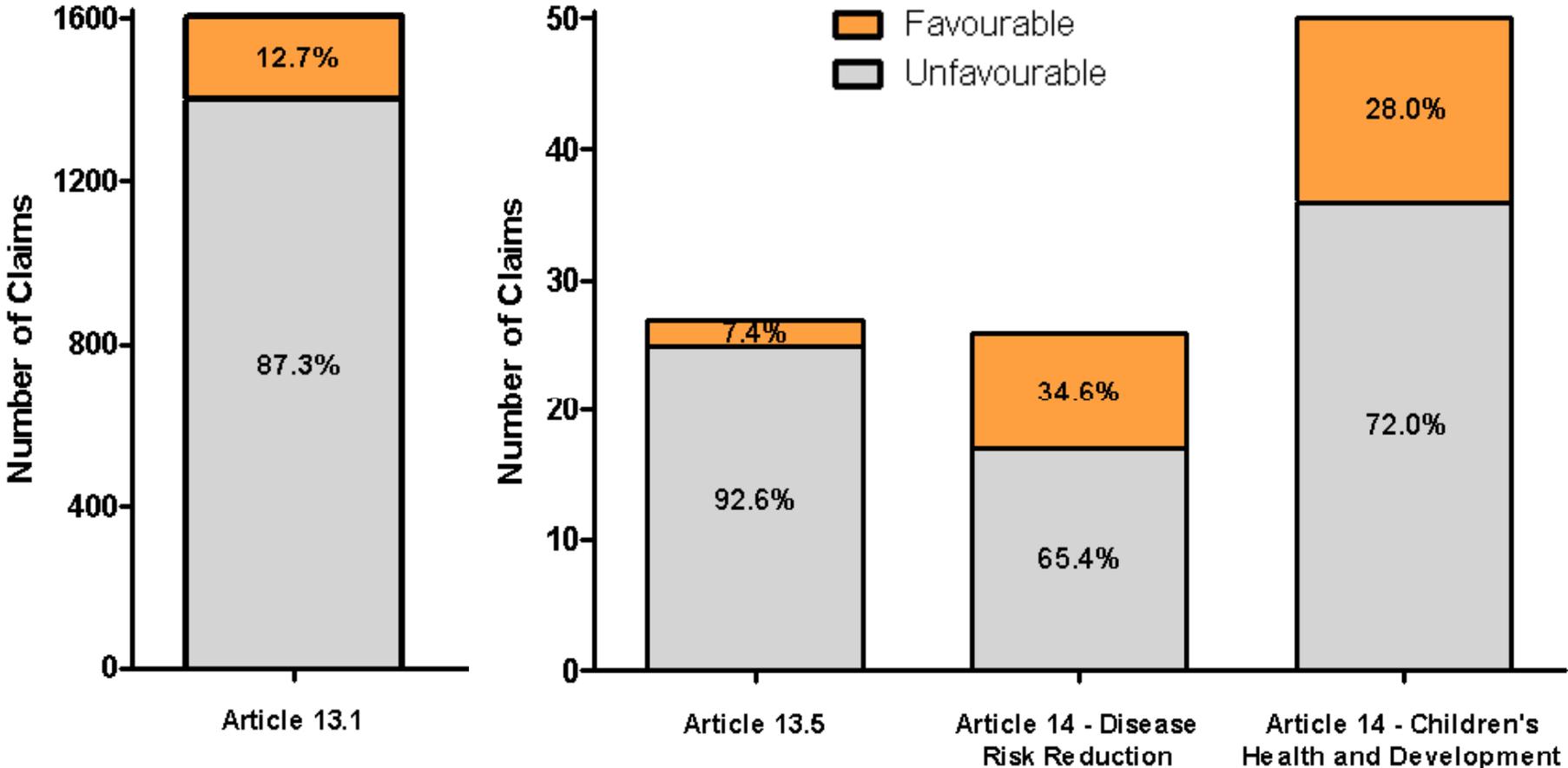


Key Points

- The point of the legislation in the first place
- Progress to date
 - Winners and Losers
 - Understanding EFSA Committees and Working Groups
 - Fallout onto other legislation
- Is it working so far?
- The future
- Will innovation suffer?
- Are we benefitting the consumer?

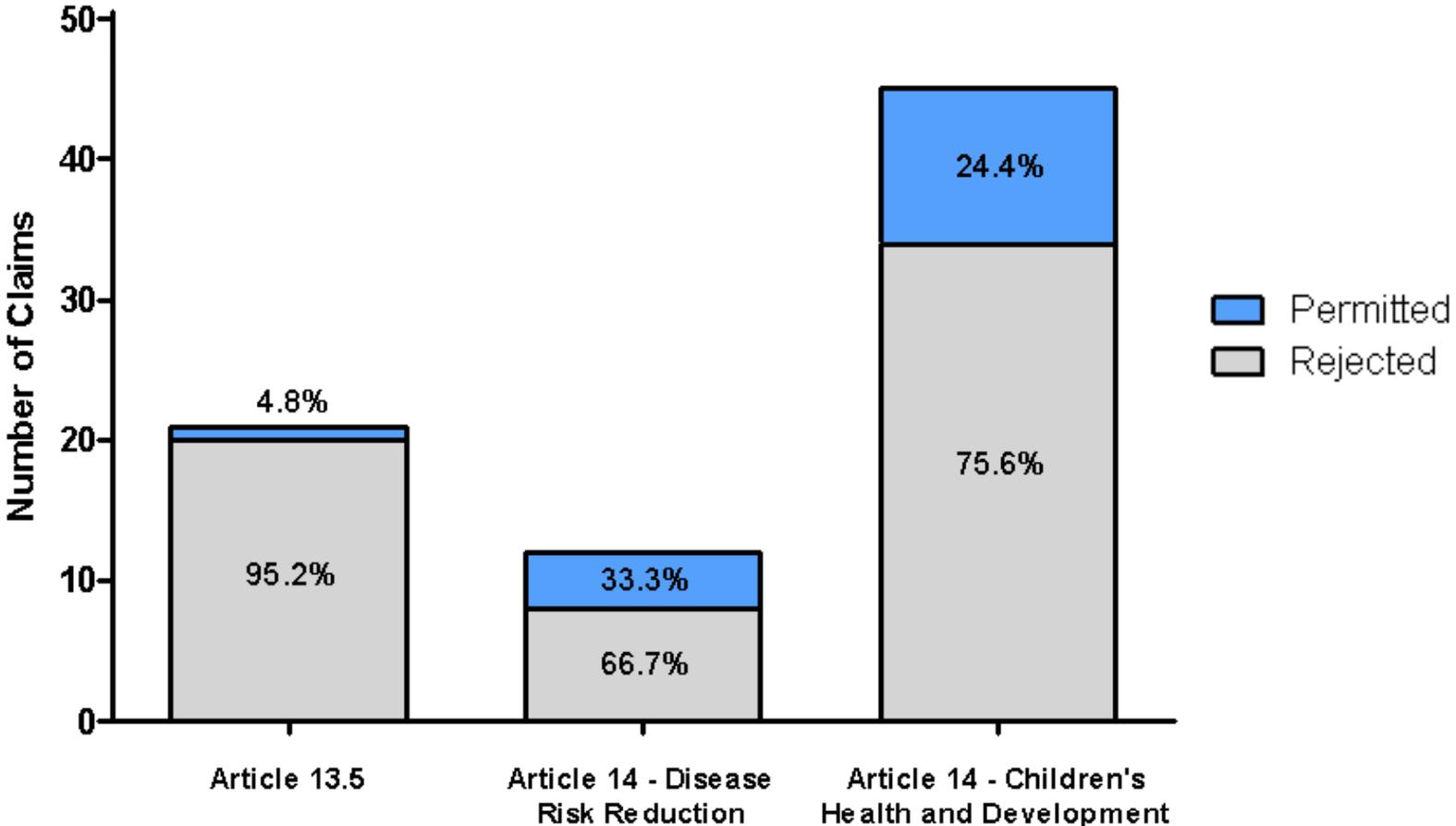
Progress to Date

- Number of claims given a favourable opinion by **EFSA**



Progress to Date

- Number of claims formally approved by the **Commission**



Winners

- Most vitamins and minerals have a range of claims they can make
 - E.g. Calcium and claims related to bone and teeth; muscle function and neurotransmission; blood coagulation; energy-yielding metabolism; function of digestive enzymes; cell division and differentiation.
- DHA and omega-3's
 - Brain, eye, heart claims for general population and children
- New Innovative ingredients
 - Water-soluble tomato concentrate
- All sorts of claims for chewing gum
 - Xylitol, polyols, sugar free gum, etc.

Losers

- Probiotics
 - EFSA consensus and expertise in this areas seriously questioned
- Weight loss (and related) ingredients
 - Most have failed
- Botanicals (so far!)
- Proprietary formulated products and combinations
- Antioxidants (in general)
- Immunity claims (in general)

Understanding EFSA Committees and Working Groups

- The power-brokers...the plenary does not have the whole story but has the last say
- The Plenary can over-rule the decision of the Working Group
- It is clear that there are key potential opinion formers in the process
- The more experts that volunteer for EFSA, the greater the possibility for scientific discussion and debate prior to the implementation of key decisions
- The opinion formers may well be reluctant volunteers in many cases and would welcome argument

Committees and Working Groups

		Acronym
NDA Plenary		NDAP
Standing Working Group Claims		SWGK
Sub-Group 1	Gut/Immune	GI
Sub-Group 2	Cardio/Antioxidants	C/A
Sub-Group 3	Bone, Dental, Connective Tissue	BDC
Sub-Group 4	Weight, Satiety, Physical, Performance	WSPP
Sub-Group 5	Mental Nervous System	MNS
Sub-Group 6	Characterisation of Botanicals	CB
Food Allergy		FA
Infant Fomulae		IT
Novel Foods		NF
Population Reference Intakes		PRI

EFSA Health Claims Experts on <1 NDA Committees

Name	Country	Number of Committees	Committee
VAN LOVEREN	Netherlands	6	NDA, SWGC, GI (C), C/A, FA, NF
SALMINEN	Finland	5	NDA, SWGC, GI, IF, NF
PRZYREMBEL	Germany	5	NDA, SWGC, BDC, IF (C), PRI
BRESSON	France	5	NDA, SWGC, GI, IF, PRI
VERHAGEN	Netherlands	4	NDA, SWGC, CB (C), NF
TETENS	Denmark	4	NDA, SWGC, WSPP (C), PRI
STROBEL	Germany	4	NDA, GI, FA(C), IF
STRAIN	Ireland	4	NDA, SWGC(C), MNS (C), PRI
MARTIN	France	4	NDA, SWGC, C/A(C), PRI (C)
LOVIK	Norway	4	NDA, SWGC, GI, FA
FLYNN	Ireland	4	NDA (C), SWGC, BDC(C), PRI
FAIRWEATHER-TAIT	UK	4	NDA, SWGC, MNS, PRI
AGOSTONI	Italy	4	NDA, SWGC, IF, PRI
TOME	France	3	NDA, GI, PRI
SANZ	Spain	3	NDA, SWGC, GI
SAARELA		3	GI, IF, NF
NEUHAUSER-BERTHOLD	Germany	3	NDA, NF, PRI
MOSELEY	UK	3	NDA, GI, NF
MARCHELLI	Italy	3	NDA, FA, NF
LAGIOU	Greece	3	NDA, FA, NF
HEINONEN		3	SWGC, C/A, NF
GOLLY	Ireland	3	NDA, SWGC, NF
KORHONEN	Finland	2	NDA, SWGC

EFSA Opinions

- Whilst EFSA does allow the applicant to review the draft, it never changes its mind on the outcome of a given opinion
- Whilst there is a public comment period and lots of people submit detailed scientific arguments EFSA never changes its mind on the outcome of a given opinion
- A new application is nearly always required taking into account EFSA's rebuttals to such comments

EFSA Opinions

- Beauty is in the eye of the beholder...
- The larger the group the more chance a fair consensus is achieved
 - Perhaps rotating experts could help keep the approach more impartial
- The decision on whether to deliver a positive or a negative opinion is made fairly early in the review process and the rest is just aligning the detail

Deficiencies of Health Claim Applications Noted in Negative EFSA Opinions

Scientific Deficiency	Article 13.1 Claims	Article 13.5 Claims	Article 14 Claims	
			Disease-Risk Reduction	Children's Health and Development
Insufficient characterisation of the food/food constituent	16%	16%	12%	28%
Claimed effect was not considered a beneficial physiological effect	37%	20%	29%	25%
Cause and effect relationship was not established	78%	100%	100%	100%

The fallout onto other legislation

- In theory you can do novel foods and health claims in parallel
- We need to ensure that this remains the case to save time to market
- EFSA treats each separately
 - E.g. Betaine has positive health claims opinion but has been specifically rejected as a novel food (because of a negative opinion of safety from the same panel of EFSA)
 - This is OK in that you cannot sell it until novel food issues are resolved and it is approved

Is it working so far?

- Its getting better as it progresses (and more positive opinions are coming out)
- There will at least be some claims to chose from
- Innovators (e.g. Provexis) are rewarded
- The science is being “rigorously” assessed
- There some irritating inconsistencies in approach
- There are some very ingrained opinions on both sides
- The real “experts” in many cases are prevented from being involved because of perceived impartiality which is a huge problem for the probiotics industry

The Future

- Member States have more responsibilities for pre-checks (they are taking more time reviewing dossiers before accepting)
- EFSA reorganisation will involve central applications desk for communication with applicants (one size does not fit all however)
- There are fundamental problems with probiotics that can only be resolved by changing the EFSA committee membership
- More experts should volunteer

The Future

- Botanicals are set to be a complete nightmare
 - So far the industry has only bought time and “words” from the Commission
 - EFSA is unlikely to change its approach
- Medical Device registrations are being looked at in some cases but product applications claims are really limited and eventually this avenue will probably be closed

The future?

- Will there be a recast of the Regulation?
 - Probably not
 - Expert certification and self assessment with scrutiny would be a progressive approach...
- Will there be amendments to clarify and tidy?
 - Probably
- Will the fundamental principles of scientific assessment change?
 - Almost certainly not

Will Innovation Suffer?

- Bad innovation (the “cowboys”) will be out of the game
- For a number of existing ingredient groups it will reinforce messages and harmonise across Europe (vitamins, minerals, omega-3s etc)
- For probiotics it will kill the industry unless consensus is achieved
- It can be great for brand new products that are well researched (e.g.) Water Soluble Tomato Concentrate

Are we Benefitting/Protecting the Consumer?

- The Commission think so
- The member states think so
- Industry is divided
- The Parliament are starting to question this fact and will make increasing use of the scrutiny procedure in future
- The consumer groups are not entirely convinced themselves
- So the next few months will be just as interesting as the last...

Thank You

Nigel Baldwin BSc, CSci
nbaldwin@cantox.com
+44 1252 400505

