

Kill Oil

(AB) No legal requirement  
Why an issue?

(JB) Almost a non issue.  
More Proprietary rights to an ingredient.

(AB) Does need to comply?

(JB)

(AB) Yes it is kill oil - safety did not need CG  
Who cares?

(SM) Comp g becoming mandatory  
Can enforce a comp guideline

(JB) Condition of listing - written into definition of ingredient

(SM) Can comp guidelines be part of ingredient rule.  
Not mirror list of containers.

(JB) Can add leaf  
Requirement of listing, not comp guidelines

(JB) Requirement of ingredient.

(AB) Do has capacity to review efficacy.

(AB) Dosage  
Look at dosage and efficacy of medicine.  
Evidence to support use.

Questions about therapeutic use. Diverse pick up in  
Post Market.

Cannot look at efficacy of new listable substance.

Has to be new  
Sign off on active ingredients.

RG Comp guidelines not mandatory.

Work around  
No docs to describe.

Something in place  
Likely to arise.

Any sponsor can put any kill oil  
have an own guideline.

Different sponsors can use different kill oils  
No issue

① Need legal underpinning → clarity

② Commercial - exclusivity of substance  
- Use exc

Is exclusivity something that should be considered

(MWS) Train out of control

Are they delivering what we need?

Legislate or find alternative

(RO) Task - original compositional guidance

(LB) Essential same, different paradigms.

How are they created?

(AB) Concerning

(BW) Specification criteria

- Periodic 10 fold lessening of

paradigm - 1.6 to 2

transfer .1 to .2

not nearly nice or clean.

By broadening criteria, compromising safety.

1st product higher quality

(NB) Refer further, quality declined → different substances.

Quality hasn't changed

Matter of safety

(RO) less than allowed in fish oil

From a safety aspect non issue.

Markets were evaluated for safety

(HW) New substances - evaluated and added

Description

(HW) Sponsor B, same but different - is it sufficiently similar

(RO) Don't submit to TGA

(JB) Can't know if they let us know.

(RO) Market and shot up.

(HW) Significant differences e.g. fatty acids.

But safety.

(HW) Clovidin - narrow parameter

(SM) Fatty acid composition

1 / 1  
Reviews of development of concentrated fish oils  
(SM) Attach fish<sup>oil</sup> base - deliver<sup>not</sup> EPA  
Function - 2 separate types of substances  
Revised guidelines  
Food products very different from fat.

(LB) Price

(RO) Krill oil

Fish oil (1 or 6 capsules/day)

2 sponsors -

(RO) Krill oil not concentrated.

Taxa B. astaxanthi

(LB) AZA

Aquamar

(LB) 2009 - show where safe

(RO) Po 2-3

Astaxanthin 110-150 - less than 150

that is the active.

(AB) USP monograph

Will create guideline

Don't know what will be on it.

(RO) "No recan, no advice

Dilemma with various sponsors

Opportunity to review role of compositional guidelines

(RO) 3rd option

- 2 different comp guidelines

- differences on register

UB Are they different substances

(AB) look different.

(SM) Accept

New substance -

Analogs - separate substance, different

Difficult how assessed.

1985 1985 - Lancer Garlic isv Garlic

Range of comp guidelines depending how produced.

Ased, aqueous

All different

Navay called garlic - class

Fits into some categories.

Class of kill oil

Different substances

(JB)

How Navay produces intensity variable.

JB Analog - racem - difference is how chemical

Fingerprint profile

Navay profile variation.

(HU)

Different solvents

Solvent does

Navay variation

Processing

(RO)

"Solvent solver"

Navay issue - AMN : Nav + Part + Prod

Not specific on preparation.

(AB)

Issues

Not sure Options are

Option 1 or 2 - accept old or new

(RO)

Either, or, both

(JB)

Old guidance stays.

Options - do not contain our list of

Will have to face regulatory action.

(SM)

Focus on fish oil, kill oil - fatty acid content.

Based on solvents - acetone pulls out fatty acids.

Look at profiles in detail - acetone different from alcohol.

2 different preparations

Based on extraction method  $\Rightarrow$  different profiles.

(SM)

2 - acetone

Other organic solvents BP conditions.

2 ways deal with kill oil -

How many comp guidelines for fish oil

(JB)

Multiple.

(JB)

C

JP  
Neptune  
LAKER

The EU say the same

AB Influence - not difference between Neptune and  
Aker Biomarine (leaves EPA OMA) influence our  
decision.

JP Compared in EU - said the same.

AB Data on water efficacy  
biomarkers of constituents  
biological activity

SM Neptune - different biological activity.  
Substance differences between substances.

LB On weaker, or stronger

~~JP~~ ~~Neptune - similar enough~~

~~Similar enough~~

AB Concede EU - similar enough.  
Demand - further action  
Quality definition of product.

HW What advantage

AB How in practice  
Clear dosages different  
lowering triglycerides  
Difficult for consumers.

HW Fish oil different names - confusion.

PO 2 products both with kill oil  
Sponsors hold evidence.  
Discofia to consumer

Consumer - still told how to use

AB When for industry if 2 guidelines  
USP in a year's time.

When ingredients separated in to 2.

JB enzymic - hexan and ethanol - BP solvents

When do we draw the line.

(AB) Fish oils overlap.

(LB) Multiple generic - new standard - ? workable.

Review role of compositional guidelines

hexan - reflect difference in quality with USP  
cons in place.

RV compositional & difference between ingredients.

(RO) All people comply with krill oil

Accept 1

Set up a standard for short period of time.

(LD) Procedure - GSK plus.

Similar reason.

How different is different and does it matter?

(MS) Listed material - nothing wonderful

established product

Registration - innovation

Does it count in?

Jamy - fish oil CA

(SM) 2 compositional guidelines - out to industry  
consultation

1 comp guideline

Procedures - function of TGA has to fit in

national medicine

Significant issues

chemical perspective - 2 eg of collapsible/combined.

If comp g broad not taking into account  
individual components.

Revise

AB

RO Second material not evaluated - not safe.

Suspect until shown to be safe.

JB Different on quality, safety

What part of Act to cease supply

Different substance not eligible for listing

SM with specification is safe. even though different.  
No concern re safety issue - but an distraction.  
Solvent extraction method result in different constituent profile.  
Now, in 10 years - separate.

JB When with herbal substances  
Standardised against different compounds.

SN No concern re safety  
Could be same class of substance  
Class - Kill oil. 2<sup>nd</sup> compositional guidelines  
Value listed - critical  
Kava significant derivation  
Kava - ingredients

- Particular extract - criteria for listing - by default comp guideline

AB ① Kill oil Listable substance? whether comp guideline or not.  
written in requirements.  
non-at present.

Is acceptable whether comp guideline

RO Not a restriction

② No major concerns re safety

Products on market eligible to stay there.  
Approved listable substance, no safety concern.

2 OK from safety

No formal evaluation presented to AECM.

Based on material input.

③ Different solvents, different constituent profile.

Fish oils

separate guideline

different comp guideline

Neptune and Superba

AZPA would not want their guideline notified

ENZ motif - different.

What is the shape of comp guideline

Not for safety, only to provide constituent profile.

④ Acknowledges USP underway + any advice would  
be eclipsed with USP monograph.

⑤ Review role of comp guideline  
market advantage, exclusivity

Acknowledge permitted for use, irrespective of whether compliant with guidelines or not

(LB) IP solves-

(PO) Expand comp guideline

Give sponsor chance to provide submission. -

(CB) Bringing to APCM

↳ commercial aim

(MS) Role of competition guidelines.

Shared info between ourselves and

- no new data

(AB) Rebuttal around safety would have come out.

(PO) Broader comp guideline, no safety concern.

First applicant chance of rebuttal

(AB) Accept revised?

(PO) Yes

(AB) 2 guidelines

(CB) Differentiated - solvent-

(2) - not safety

- quality? not sure.

(DW) Hebs - differentiated on purity, prep, solvent.

(AB) 1 - narrow, make error.

2 - - safe, recognise different product and quality, reflect in dosage.

Other compounds also differ significantly.

Perhaps not enough.

(PC) Advantage of having Kill 1 or 2

→ just confusion.

(AB) different quality, different dosages.

as happens with everything else.

(SM) Can to time with issue

• all guidelines - revise current guideline.

• all meet

• overused in a year's time.

• Academic

(CB)



BW

AB Vote

① ACCM recognize Kill oil as approved listable substance  
inspection of whether it complies with the CG

② Based on presented data, ACCM identified no safety  
concerns in either CG, providing <sup>Kill oil is</sup> identified.  
and BP compliance solvents

③ ACCM recognize a difference in <sup>processes</sup> solvents used, resulting  
in different constituent profiles ~~that result in some~~  
~~and~~ variation in quality parameters in final product.

Not uncommon in natural products. Therefore not a strong  
argument for more than 1 comp guideline to define  
safe kill oil. Noting variations in active  
constituent profile will be reflected in final  
dosage of therapeutic product. substance.

1 ~~recognition of~~ Do us go with Option 2

SM. BP solvents

AB Vote

Option 2

③ ~~④~~ ④ Note USP in development

⇒ ~~⑤~~ <sup>⑤</sup> Re-examine role of compositional guidelines

⑥ Whales starving as a result  
also

Kill Oil

No legal requirement

Why an issue?

Almost a non issue.

More Proprietary rights to an ingredient.

Does need to comply?

Yes it is Kill oil - safety given new CG

Who cares?

Camp g becoming mandatory

Can't write a camp guideline

Condition of listing - written into definition of ingredient

Can camp guidelines be part of ingredient rule.

Not main list of contaminants.

Can add leaf

Requirement of listing, not camp guidelines

Requirement of ingredient.

Do have capacity to review efficacy.

Dosage

Look at dosage and efficacy of medicine.

Evidence to support use.

Questions about therapeutic use provide pick up in

Past Market.

Cannot look at efficacy of new listable substance.

Has to be new

Sign off on active ingredient.

Camp guideline not mandatory.

Work around

No goes to describe.

Something in place

Likely to arise.

Any sponsor can put any Kill oil

have on own guideline.

Different sponsors can use different Kill oils

Non issue

① Need legal underpinning  $\rightarrow$  clarity

② Commercial - exclusivity of substance  
- Use exc

Is exclusivity something that should be considered  
Taken out of context

Are they delivering what we need?

Legislate or find alternative

Task - original compositional guidance

Essentially same, different paradigms.

How are they created?

Concerning

Specification criteria

- Period 10 fold lessening of

particle - 1.6 to 2

transfer .1 to .2

not nearly nice or clear.

By broadening criteria, compromising safety.

1st product higher quality

Ref - further, quality declined  $\rightarrow$  different substances.

Quality hasn't changed?

Marker of safety

less than allowed in fish oil

From a safety aspect non issue.

Markers were evaluated for safety

New substances - evaluated and added

Description.

Sponsor B, same but different - is it sufficiently similar

Don't submit to TGA

Can you know if they let us know.

Marker and shot up.

Significant differences e.g. fatty acids.

But safety.

Clonidine - narrow parameter

Fatty acid composition

Reviews of development of concentrated fish oils

Attach fish oil - advise not EPA

Function - 2 separate types of substances

Revised guidelines

Fed products very different from fish

Price

Krill oil

Fish oil (1 or 6 capsules/day)

2 sponsors -

Krill oil not concentrated

Tax B. astaxanthi

AZD

Aquamarine

2009 - show shared safe

Pa 2-3

Astaxanthin 110-150 - less than 150

that is the advice

USP monograph

Will provide guidance

Doesn't know what will be on it

No recan, no advice

Dilemma with various sponsors

Opportunity to review role of compositional guidelines

3rd option

- 2 different comp guidelines

- differentiate on register

Are they different substances

look different

Accept

New substance -

Analogs - separate subcategory different

Difficult how assessed

1985 1985 - Lancer Garlic isv Garlic

Range of comp guidelines depending how produced

Azed, aqueous

All different

Narrowly called garlic - class  
Fits into same category.

Class of kill oil

Different substances

Narrow product identity variable.

Analog - racem - difference is hand chemical

Fingerprint profile

Narrow profile variation.

Different solvents

Same does

Narrow variation

Processing

"Solvent solvent"

Naming issue - AMN, Name + Part + Prod

Not specific on preparation.

Issues

Not sure Options are

Option 1 or 2 - accept old or new

Either, or, both.

Old guidance stays.

Organizer - do not contain our language

Will have to take regulatory action

Focus on fish oil, kill oil - focus add cover.

Based on solvents - action pulls out both sides

Looks at profiles in identity - action different from old

2 different preparations

Based on extraction method -> different profiles.

2 - action

Other organic solvents. BP conditions.

2 ways deal with kill oil -

How many comp guidelines for fish oil

Multiple.

C

Neptune

The EU say the same

Influenza - not different between Neptune and  
(laws EPA OHA) influenza our  
decision.

Compare in EU - said the same.

Does evaluate efficacy

biomarker of constituents

biological activity

Neptune - different biological activity.

Substance differences between substances.

Our weaker, or stronger

Concede EU - similar enough.

Revised - further action.

Quality definition of product.

What advantage.

How in practice

Clearly dosages differ

lowering triglycerides

Difficult for consumers.

Risk oil different names - confusion.

2 products both with kill oil

Spans 1 hold evidence.

Decision to consumer

Consumer - still told how to use

When for industry if 2 guidelines

USP in a year's time.

When ingredients separated into 2

enzymic - hexan and ethanol - BP solvents

When do we draw the line.

Fish oils overlap.

Multiple generic - new standard - ? workable.

Review role of compositional guidelines

harmon - reflect difference in quality with USA  
cases in place.

RV compositional G difference between ingredients.

All people comply with krill oil

Accept 1

Set up a standard for short period of time.

Procedure - Antigo plus.

Similar reason.

How different is different and does it matter?

Listed max - not in world

established product

Registration - innovation

Does it come in?

- fish oil CG

2 compositional guidelines - out to industry  
consultation

1 comp guideline

Procedural - function of TGA has to fit in  
national medicine

Significant issues

Chemical perspective - 2 eg of collapsible/compressed.

If comp g broad not taking into account  
individual components.

Revise

Second material not evaluated - not safe.

Suspend until shown to be safe.

Differ on quality, safety

What part of Act to cease supply

Differ substance not eligible for listing

1 / 1  
either specification is safe. even though different,

No concern re safety issue - but as distinct.

Solvent extraction method result is different constituent profile.

Now, in 10 years - separate.

When with herbal substances

Standardised against different compounds.

No concern re safety

Could be some class of substance

Class - Kani oil. 2<sup>nd</sup> compositional guidelines

Value listed - critical

- Kava significant derivation

Kava - guidelines

- Particular extract - criteria for listing - by default comp guideline

① Kani oil Listable substance? whether comp guideline or not.

written in requirements.

None at present.

Is acceptable whether comp guideline

Not a restriction

② No major concerns re safety

Products on market eligible to stay there.

Approved Listable substance, no safety concern.

2 OK from safety

No formal evaluation presented to AECM.

Based on material input.

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market advantage, exclusivity



Acknowledge permitted for use, irrespective of whether compl  
with guideline or not

IP solvers.

Expand comp guideline

Give sponsor chance to provide submission. -

Bringing to APCM

→ commercial aim

Role of compositional guidelines.

Shared info between engineers and

- no new data

Rebuttal around safety would have come out.

Broader comp guideline, no safety concern.

First applicator chance of rebuttal

Accept revised?

Yes

2 guidelines

Differentiated - solvers.

- not safety

- quality? not sure.

Herbs - differentiated on platform, prep, solver

1 - narrow, market edge.

2 - - safe, recognise different profiles and quality  
reflected in design.

Other cases may also differ significantly.

Perhaps not enough

Advocate of having kill 1 or 2

→ just confusion.

different quality, different messages.

as happens with everything else.

Can to time with issue

1 guideline - revise current guideline.

2 all meet

3 overused in a year's time.

4 Academic

Vote

① ACCM recognize Kill oil as approved listable substance  
inspection of whether it complies with the CG

② Based on presented data, ACCM identified no safety  
concerns in either CG, providing Kill oil is  
and BP compliant solvents identified.

③ ACCM recognize a difference in processing  
in different constituent profiles that result in some  
variation in quality parameters in raw product.  
Not uncommon in natural products. Therefore not a strong  
argument for more than 1 comp guideline to define  
safe fill oil. Noting variations in active  
constituent profile will be reflected in raw  
doseage of therapeutic product substance.

Recognition of DO we go with Option 2  
BP solvents

Vote

Option 2

④ Note USP is developing

⇒ Review role of compositional guidelines

Whales starting as a result  
also