

A MATTER OF PRINCIPLE

Developing regulatory principles with the help of STAMP

David Wotton

DISCLAIMER

I have previously worked for a number of government agencies.

The comments in this presentation are solely my own and do not constitute claims of any position being held, or not, by the Australian Government.



Dealing with a regulator

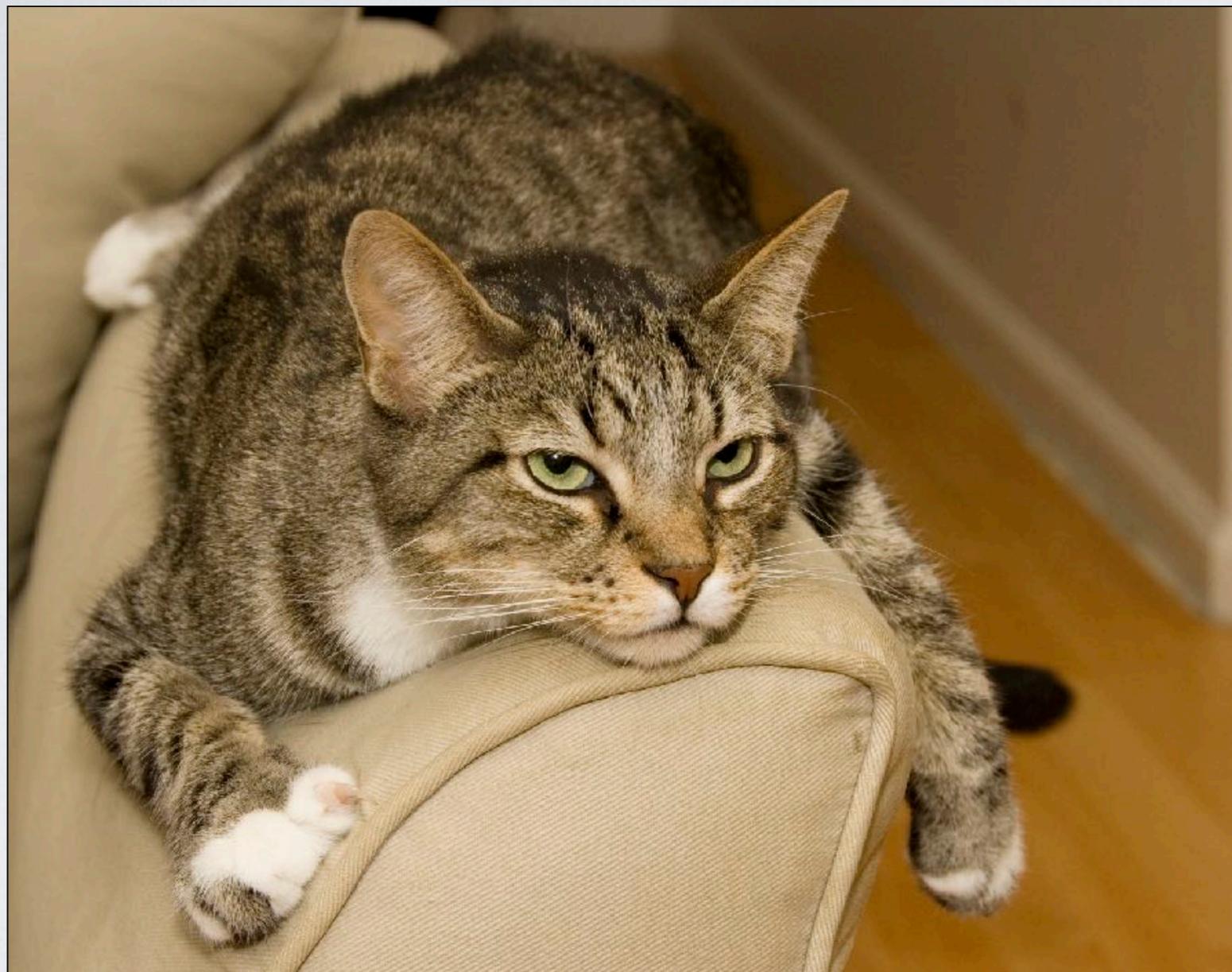




Working for
a regulator

Public's view of regulators





Government's view

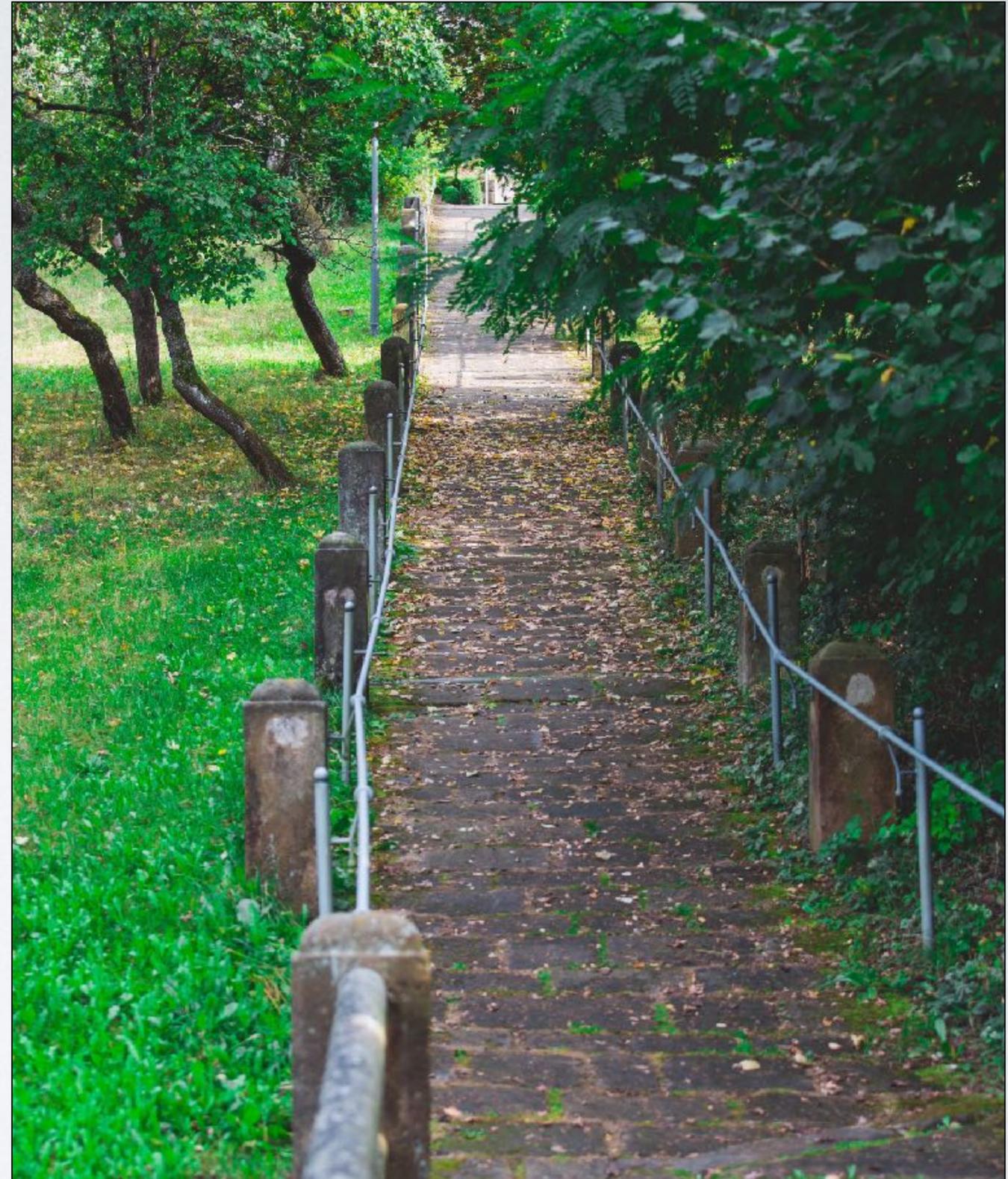
CHAPTER ONE

Why for regulators
Regulator's toolkit
Regulations, Rules, and Principles



Why for regulators

- Social/common good
- Market failure
- Political ends



Regulator's toolkit



Regulations, Rules, and Principles



EXAMPLE REGULATORY PRINCIPLE

Benefit must outweigh the risk

—International Medical Device Regulator's Forum
Essential Principles of Safety and Performance



Benefit must outweigh the risk

Assumptions

That it is possible to:

- quantify the benefit
- quantify the risk
- compare the two and determine an outcome



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Most important question:

Is enforcing adherence to this regulatory principle a useful thing to do?



EXAMPLE REGULATORY PRINCIPLE

Benefit must outweigh the risk

Example: High-rate infusion pump



ASSOCIATED REGULATORY PRINCIPLE

state of the art

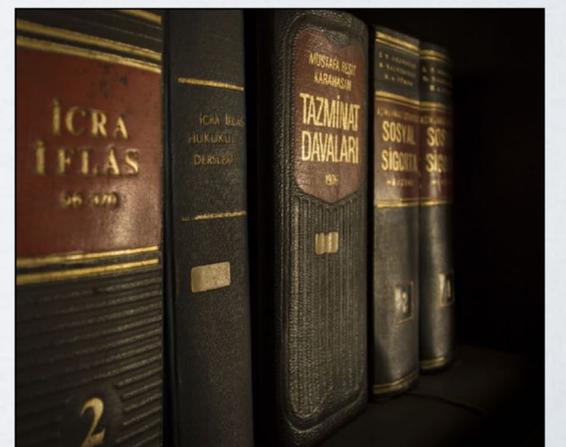
Example: High-rate infusion pump



ASSOCIATED REGULATORY PRINCIPLE

Generally acknowledged state of the art

Example: High-rate infusion pump



COMBINED

Benefit must outweigh the risk

+

Generally acknowledged state of the art

—International Medical Device Regulator's Forum
Essential Principles of Safety and Performance



PRESCRIPTION VS PRINCIPLE



Advantages

- Less arguments
- Easy to administer
- Easy to follow

Disadvantages

- Inflexible
- High regulator burden
- Possibly less efficient
- Slow to change
- Compliance \neq safety
- Can be inappropriate

Advantages

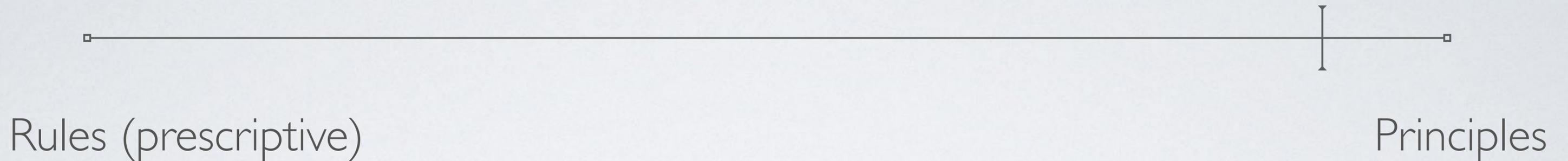
- Flexible
- More resilient to external changes
- Arguing the essence rather than compliance / checkbox mindset

Disadvantages

- By nature, are subject to interpretation and case-by-case dispute
- Difficult or impossible to administer for checkbox thinkers
- Can be inappropriate

* Please note: these lists are neither exhaustive nor complete...!

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PRESCRIPTION VS PRINCIPLE



Rules (prescriptive)

Principles

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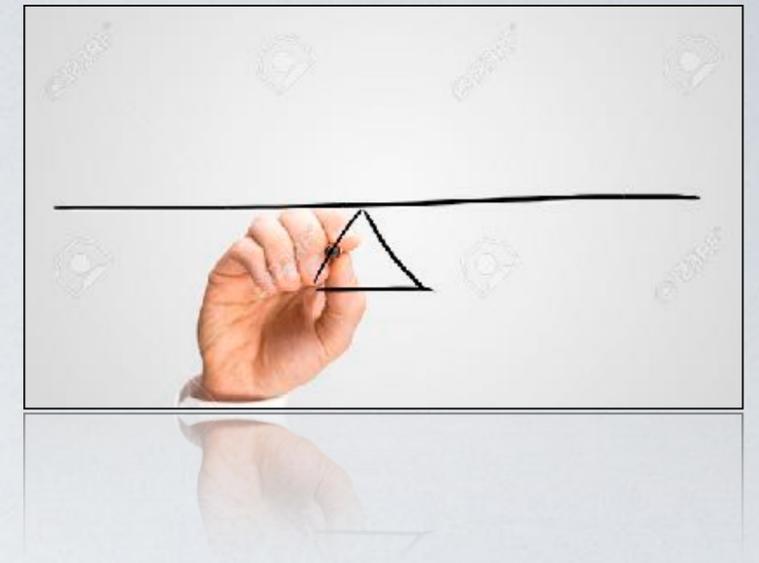
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BALANCE

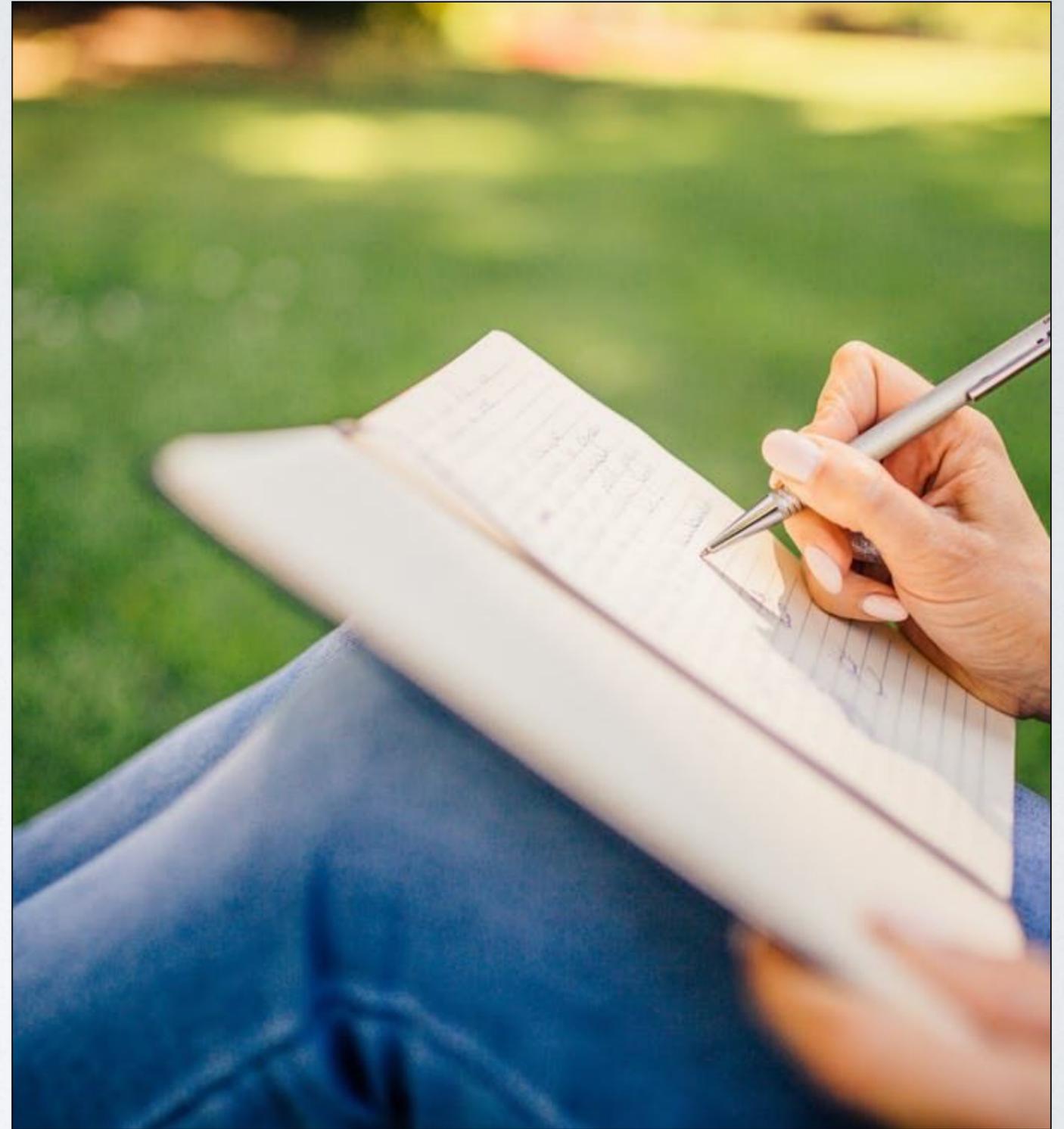


Hybrid



WRITING GOOD PRINCIPLES

Aims
Challenges
Other considerations



Aims

Efficient
Effective
Acceptable



Challenges



Other
considerations

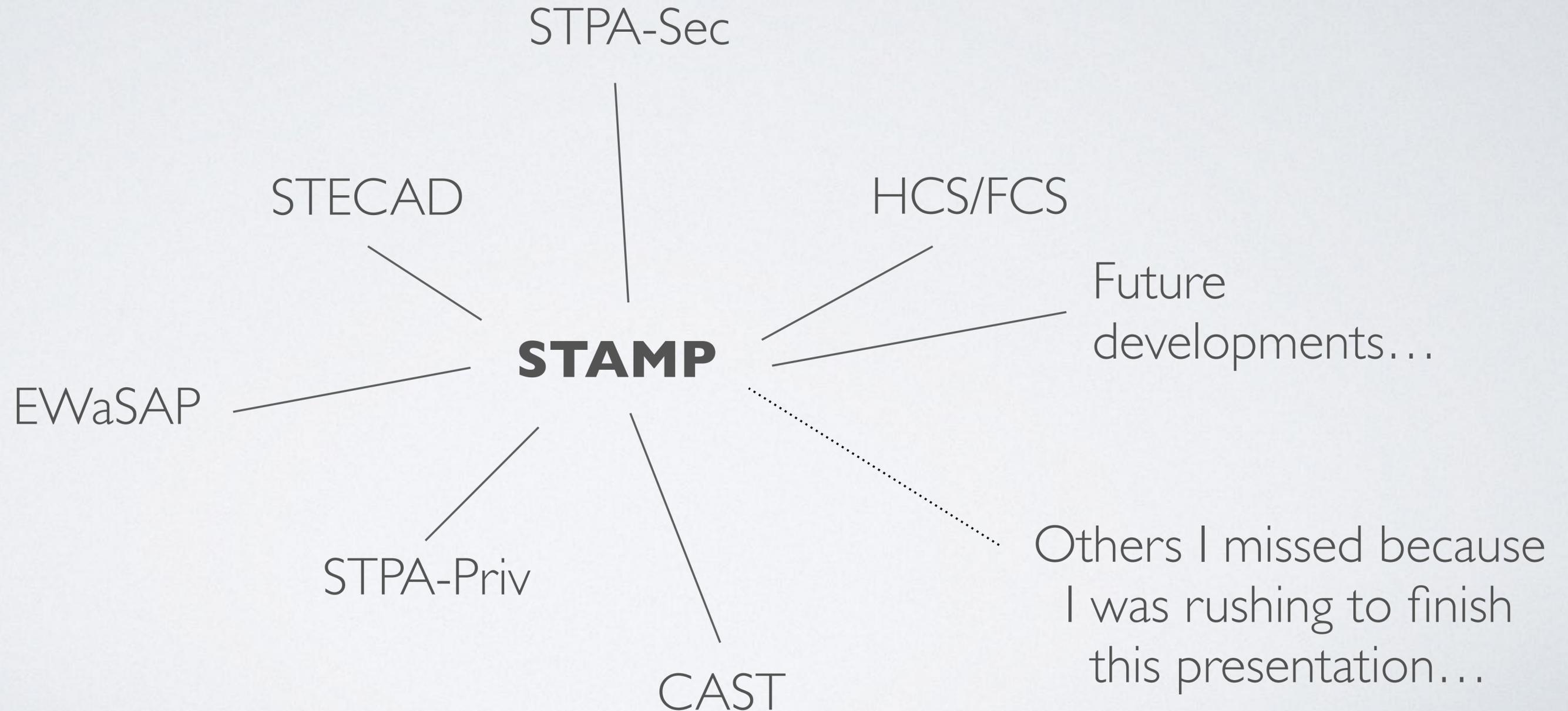


CHAPTER TWO

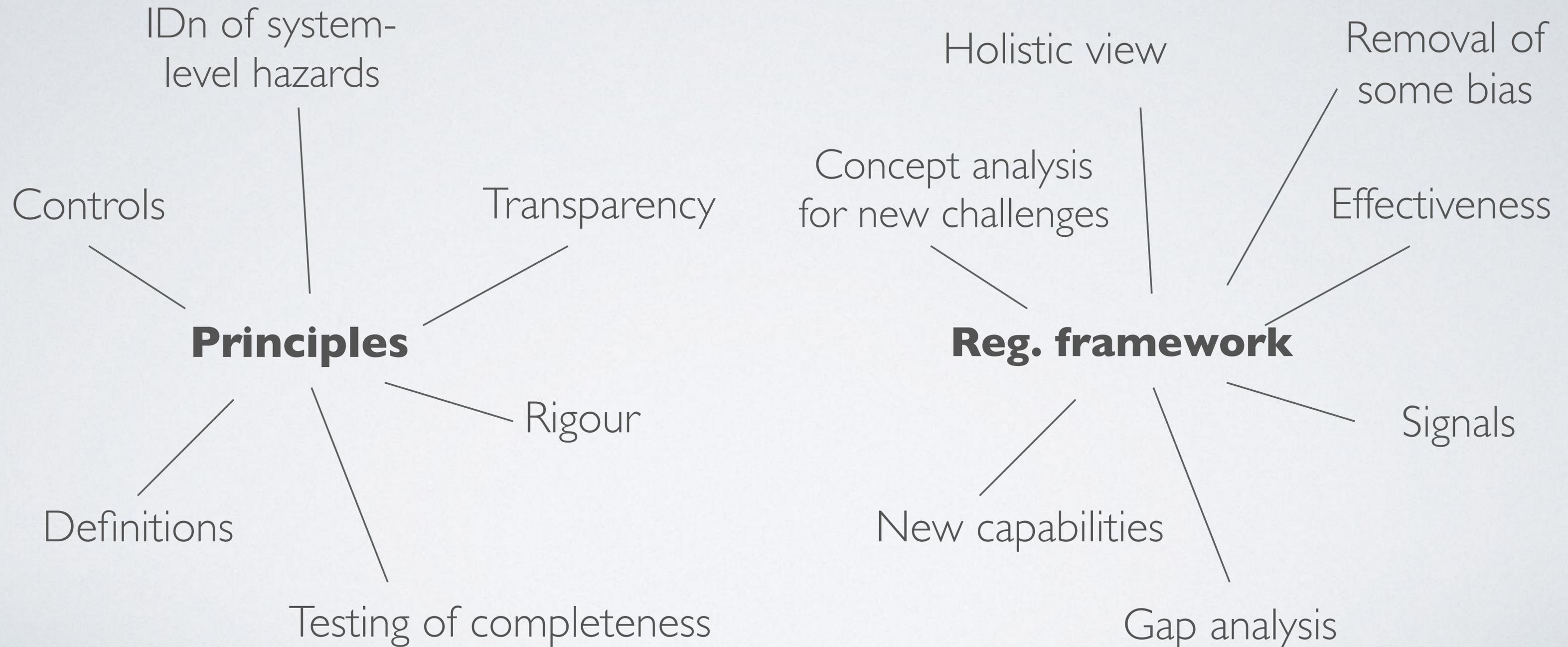
What STAMP can offer



POTENTIALLY USEFUL STAMP TOOLS



STAMP TOOLS POTENTIALLY OFFER...



STAMP TOOLS POTENTIALLY OFFER...

two **really** important things that are frequently missing:

A holistic view

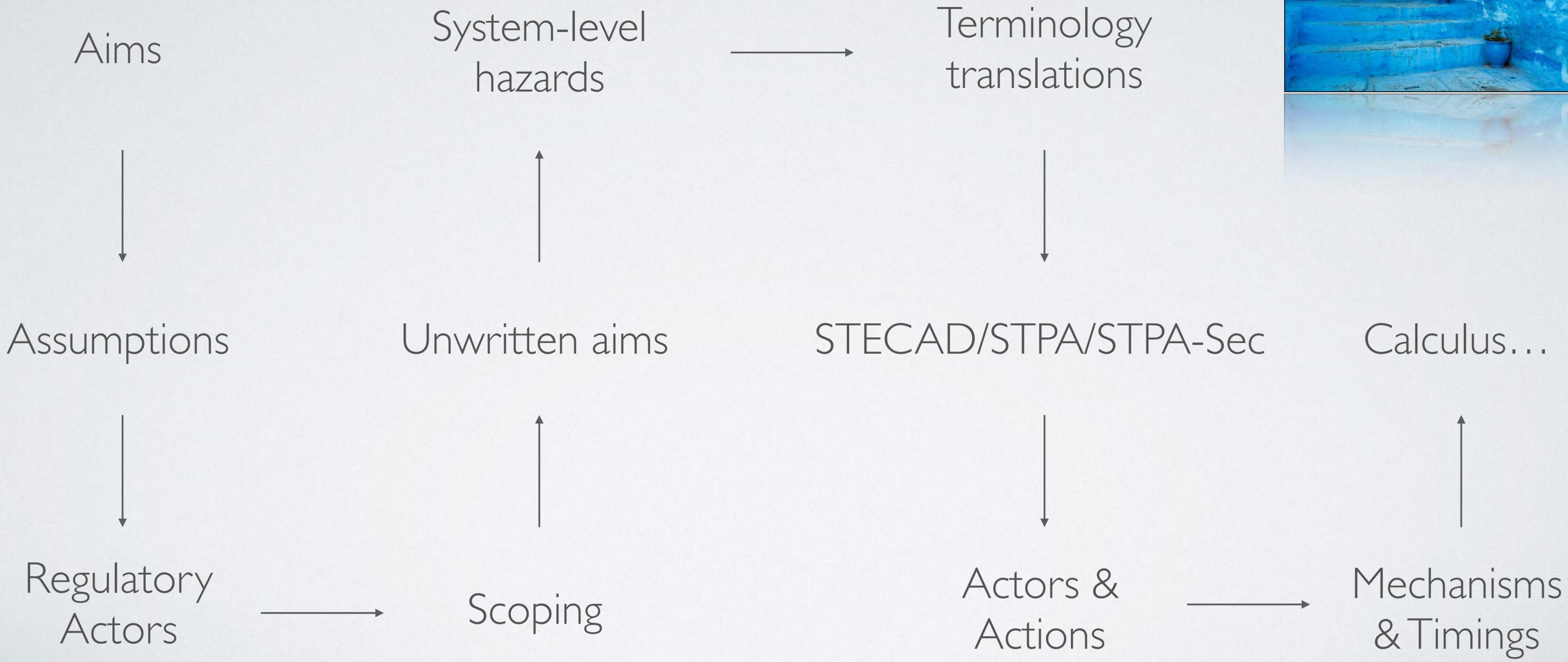
**A proactive
regulatory
framework**

ROUGH STEPS

(Iterative procedure)



ROUGH (ITERATIVE) STEPS



SOME ELEMENTS AND EXAMPLES

Regulated environment: consumer safety, protection of river quality, etc.

Example	Actor I	Actor II	Actor III	Actor IV
Actor	Regulator	Regulatee	Expert advisory group	Consumer advocacy group
Action (verb)	<ul style="list-style-type: none"> • <i>Inspect</i> site • <i>Assess/evaluate</i> data 	<ul style="list-style-type: none"> • <i>Generate</i> documents • <i>Conduct</i> clinical trials 	Assess scientific evidence	Monitor available information Advocate
Method / mechanism	Scientific method Public service methods	<ul style="list-style-type: none"> • Scientific/clinical studies • QMSs 	Scientific methods based on discipline	<ul style="list-style-type: none"> • Read reports/news • Write to agencies
Timing	<ul style="list-style-type: none"> • Inspection frequency 	<ul style="list-style-type: none"> • Market timings and cycles • Reg requirements 	As dictated by regulatory agencies (pre and post market)	Ongoing basis plus following public events or release of reports
Calculus	How to maximise regulatory aims within constraints	How to maximise profit How to protect brand and reputation	Meeting the TOR; professionalism and integrity	Are consumers being ripped off?

HERE BE DRAGONS...

Rfid chips

- Credit card
- Passport
- Access card for work



HOW ARE YOU FEELING?

HOW ARE YOU FEELING?

My guess

- Anxious
- Vulnerable
- *Angry*



A top-down
view can be
a little scary



Bureaucratic capture





BBC TV c1984

The three articles of civil service faith

- it takes longer to do things quickly;
- it's more expensive to do them cheaply;
- it's more democratic to do them in secret.

— James Hacker MP

Operating environment



Herculean
efforts...



sometimes just get you to a
bigger fish bowl

CHAPTER FOUR

Observations...

No-go areas

Communication difficulties

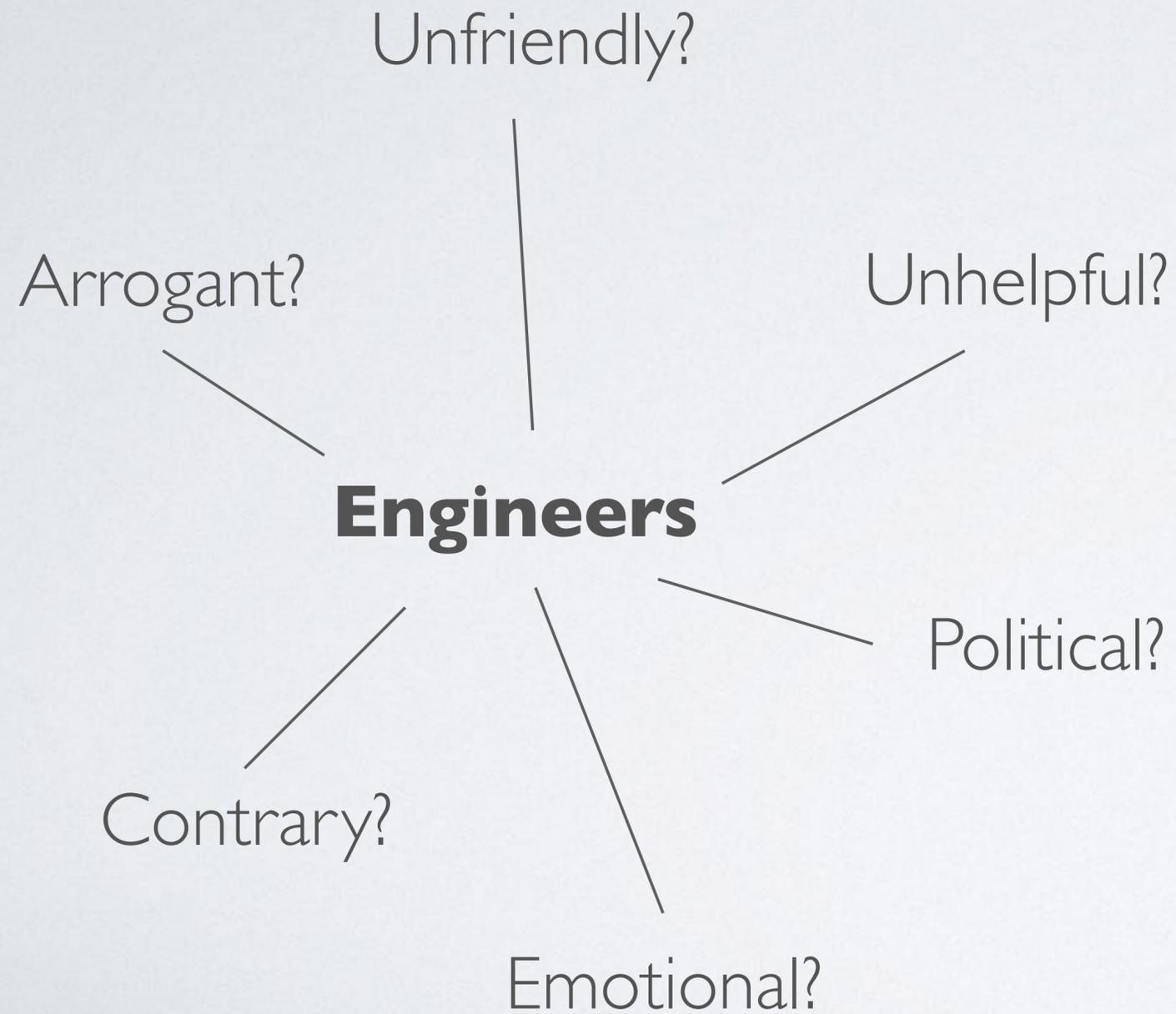
Framing





No-go
areas

BLOODY (DAMN) ENGINEERS



COMMUNICATION DIFFICULTIES

- Systematic, critical, and flexible thinking
- Different disciplines, different meanings



A CYNICAL TRANSLATION OF TERMS

	Risk management	Regulation
Technical officers	A method of managing technical risk.	Looking after the public good.
Management	Something the technical officers do; something to do with safety.	Looking after the public good while managing available resources and political capital.
Politicians	Management of political risk and a good way to justify fixed or reduced resourcing levels.	A way of managing public expectations.

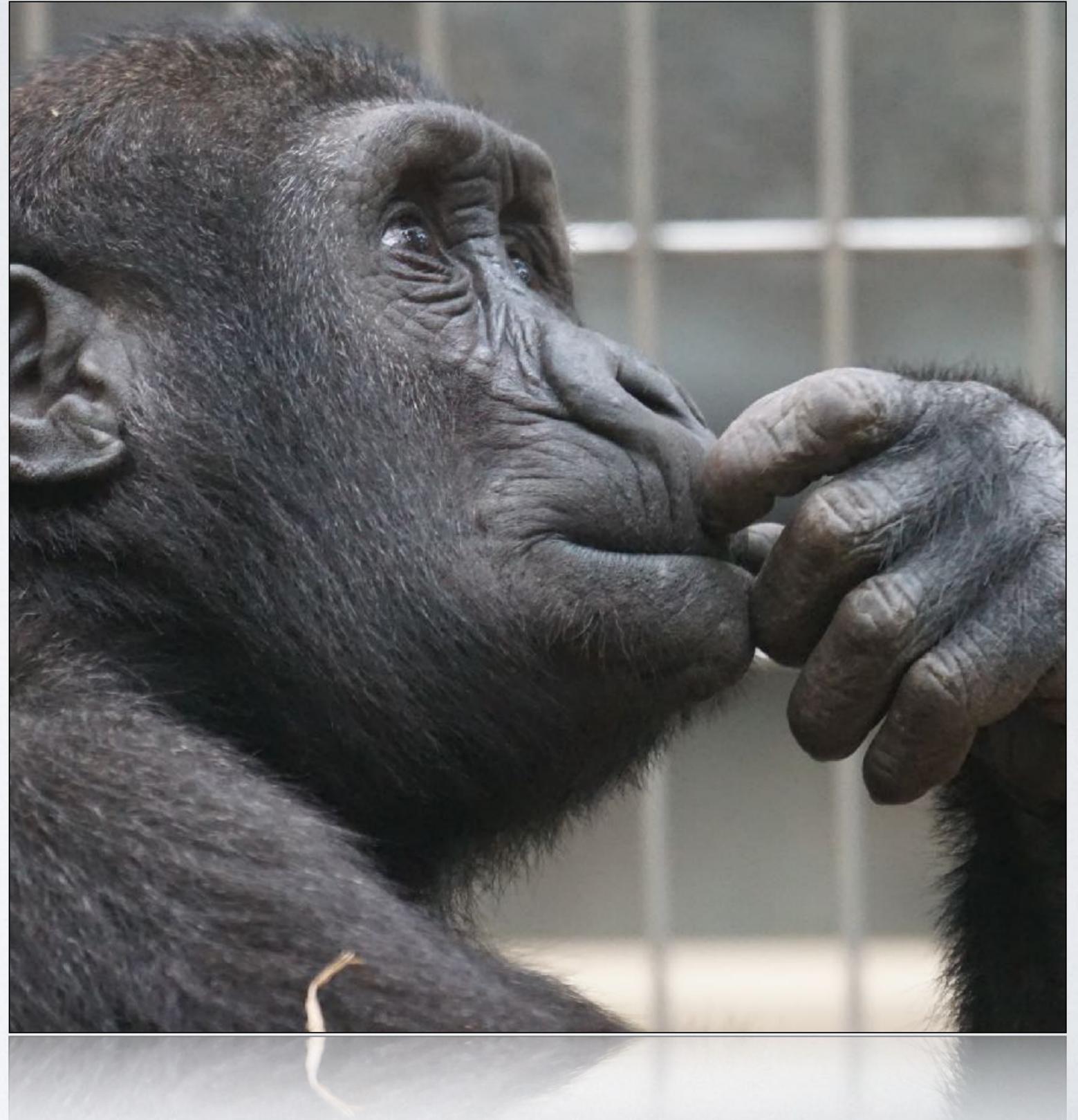
FRAMING AND TIMING

- Politics
- Society
- Disciplines



CONCLUDING THOUGHTS

Language and acceptance
Change champions
Automation





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