

ebeam Sterilization of Medical and Food Packaging enabled by Compact ebeam Lamp Technology

RadTech Chicago, May 17th, 2016

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ebeam Technologies – COMET AG

ebeam

Contents

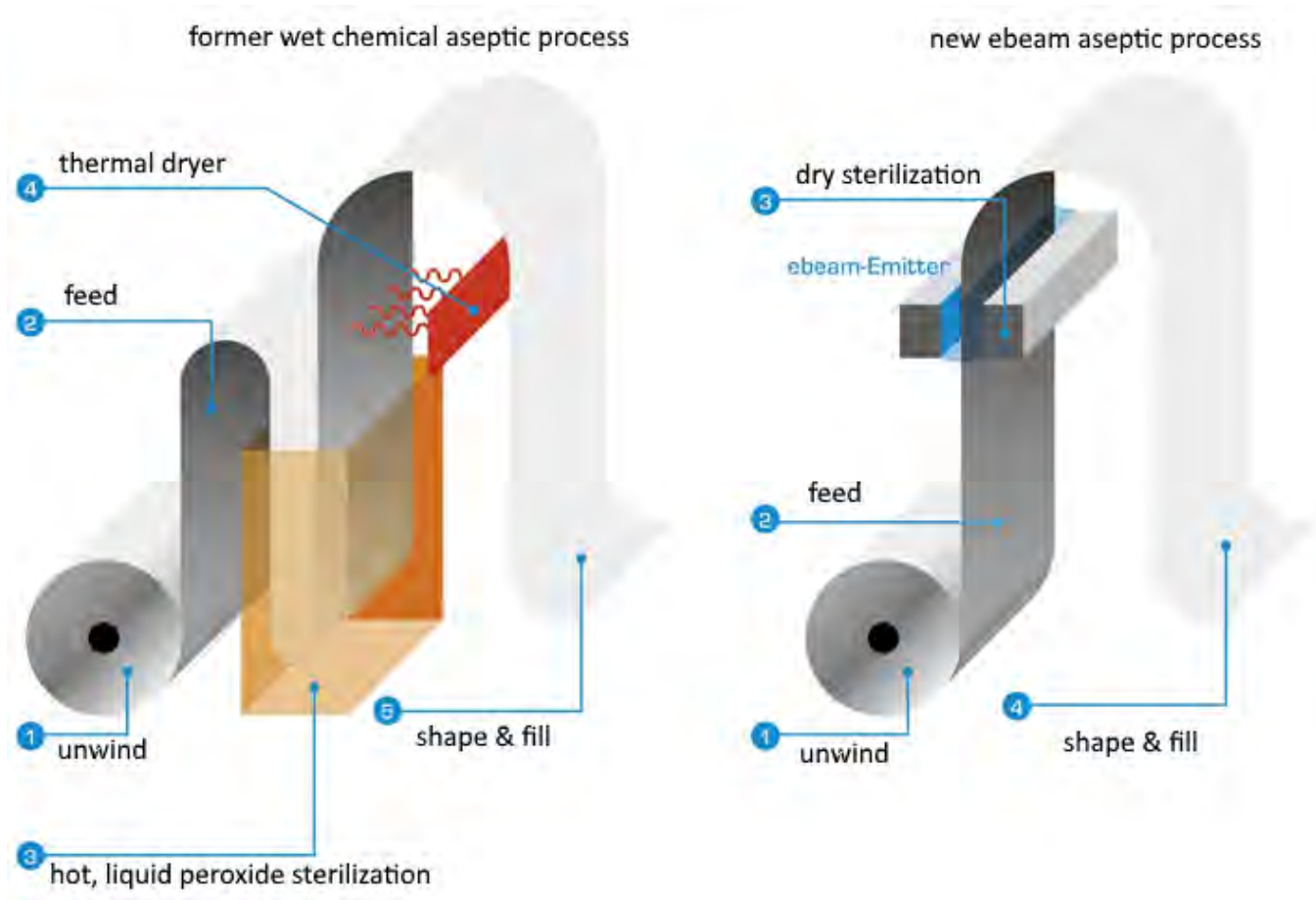
- Quick Corporate Brushover
- (Atmospheric) Electron Beam
- Sterilization Basics
 - Killing me softly
- Selected inline examples
- Verdict

ebeam



ebeam for the masses

Tetra Pak - chemical-free sterilization



ebeam for the masses

Sterilisation of Packaging Material



ebeam

<https://www.youtube.com/watch?v=WSeltaEavpo>
<https://www.youtube.com/watch?v=d36tV08ejKA>

5/18/16 | 4

COMET Group
Facts and Figures

ebeam



COMET Group

At a glance

- Founded in 1948
- Headquarters in Flamatt, CH
- 14 locations worldwide
- >1050 employees worldwide
- Net sales in mCHF in 2015: 282.3
- EBITDA margin in 2015: 12.7%



COMET Group

At a glance

Leading worldwide with x-ray, RF and ebeam Technologies



Breaking News May 2015

the first and biggest EB Power house in LE-EB



ebeam

ebeam

Electron Beam

What is it?

ebeam



(Atmospheric) Electron Beam

the 3 cousins: X-ray tube, ebeam lamp and CRT

Flood Beam (<300kV)

Scanning Beam (mainly >500kV)

COMET's e-beam versus X-ray

- Ultra-high vacuum
- Electrons are accelerated in a strong electric field
- Glowing filament emits electrons
- High voltage insulator
- At negative high voltage

X-ray

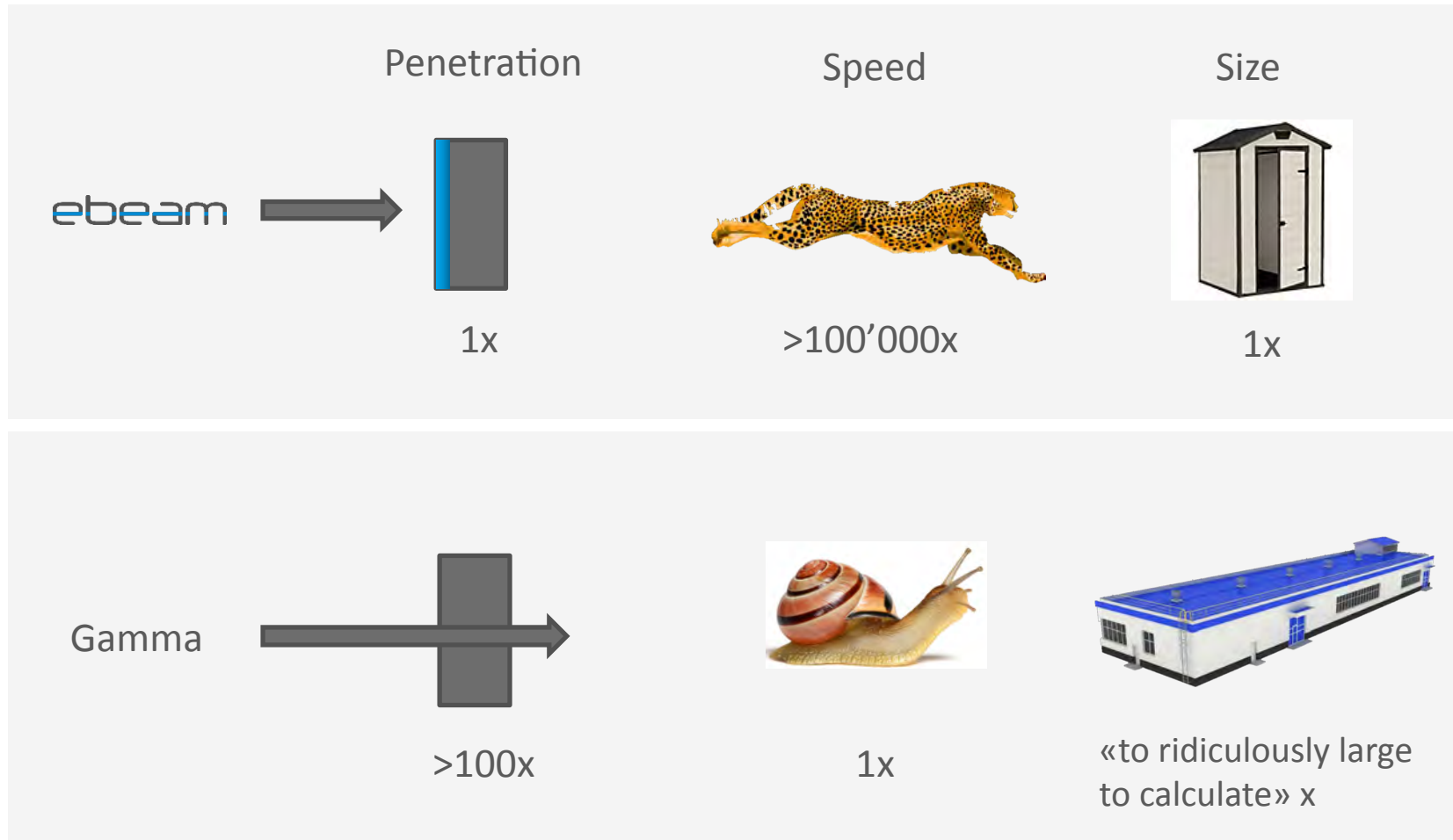
e-beam

- Electrons in Atmosphere
- Defocused electron beam
- electron shower

- Electrons in Atmosphere
- focused electron beam
- scanned beam

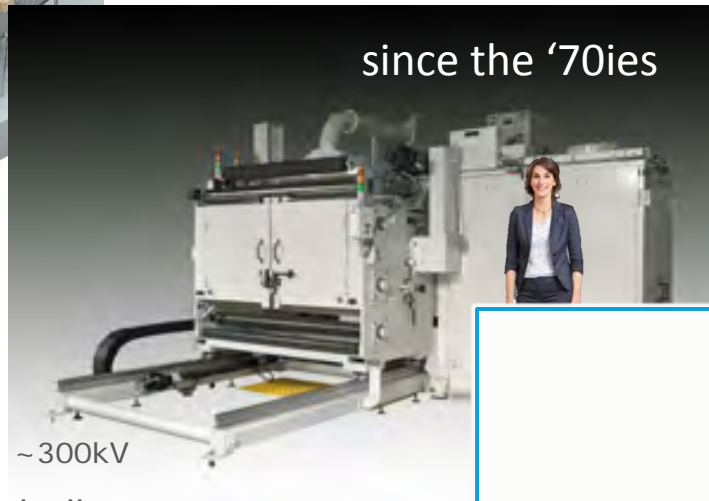
(Atmospheric) Electron Beam

Comparison to other industrial technology (Gamma)



ebeam (r)evolution

the invention of the "e-light bulb"



- the ebeam «light bulb»
- small
 - affordable
 - hermetically sealed
 - integrated vs. designed around
 - replacements within minutes

ebeam

(Atmospheric) Electron Beam

why sealed emitters make a difference

big ebeam

- large volumes
- commodity
- split processes (service centers)

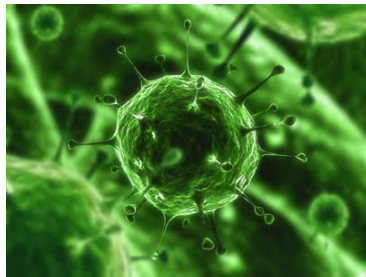
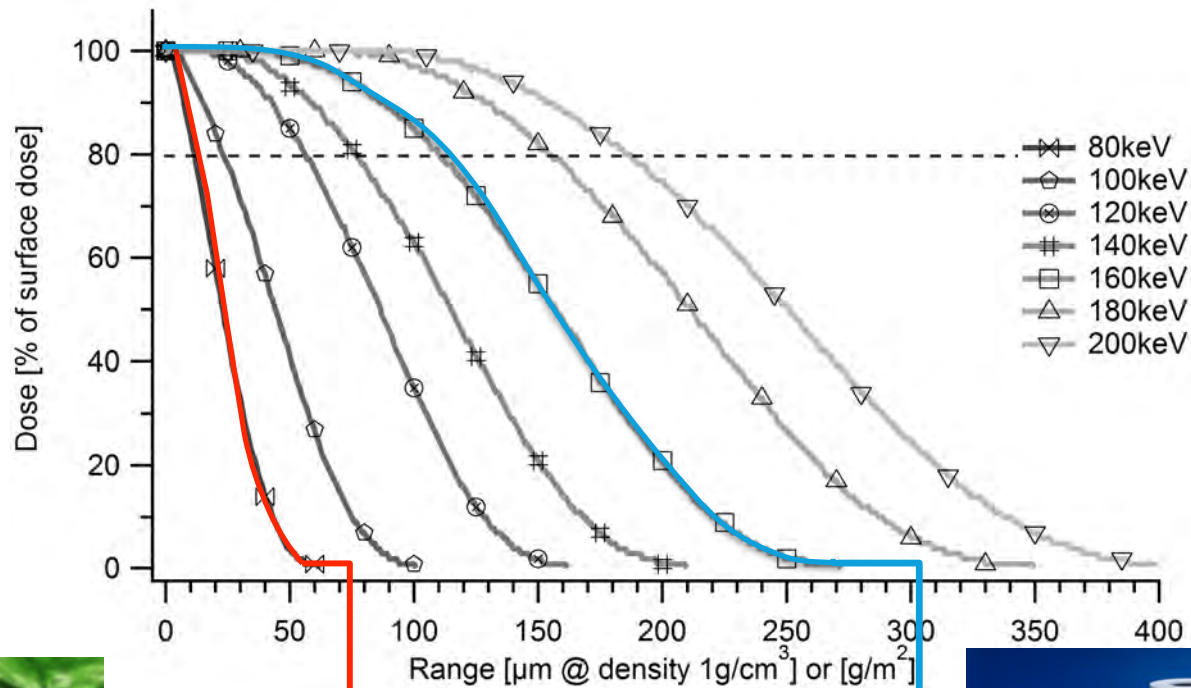


compact ebeam

- «small» volumes
- high added value
- owned and inline

ebeam Technologies

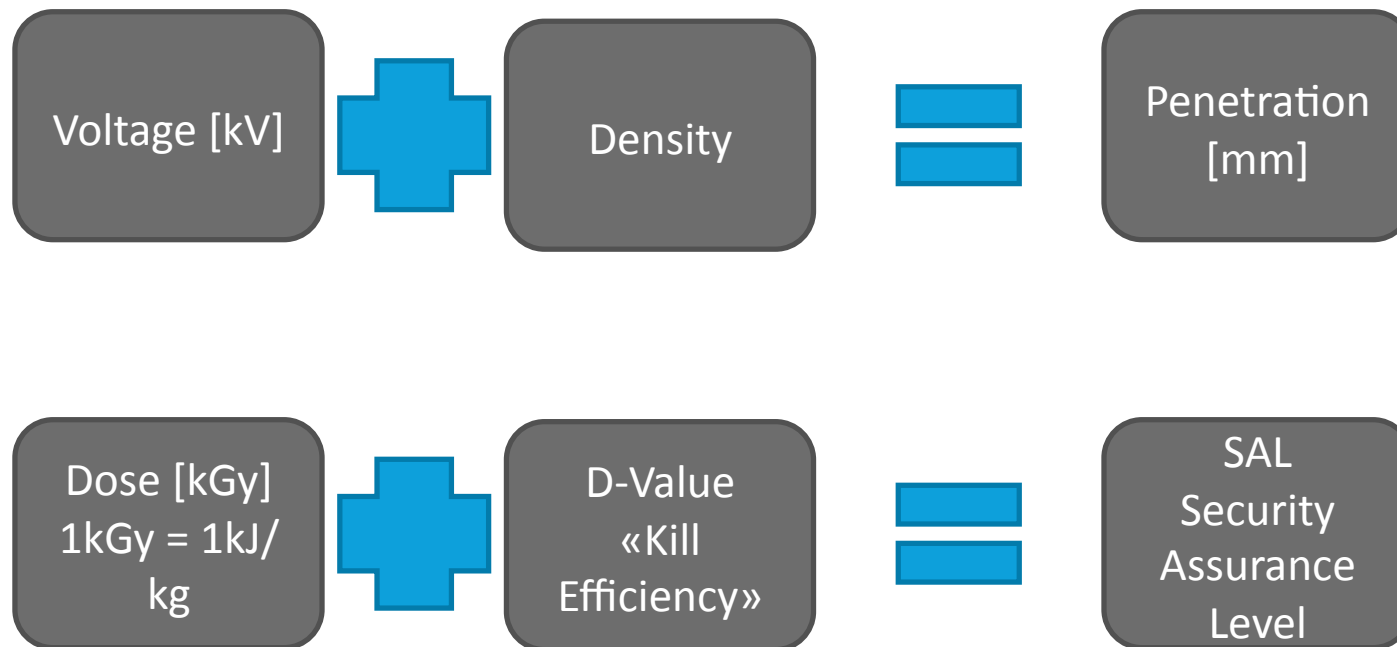
Depth – Dose Curves – Control where Effect is created



ebeam

ebeam Technologies

The main parameters in Bio-burden reduction



ebeam is COLD, CONTACT FREE and DRY Sterilization

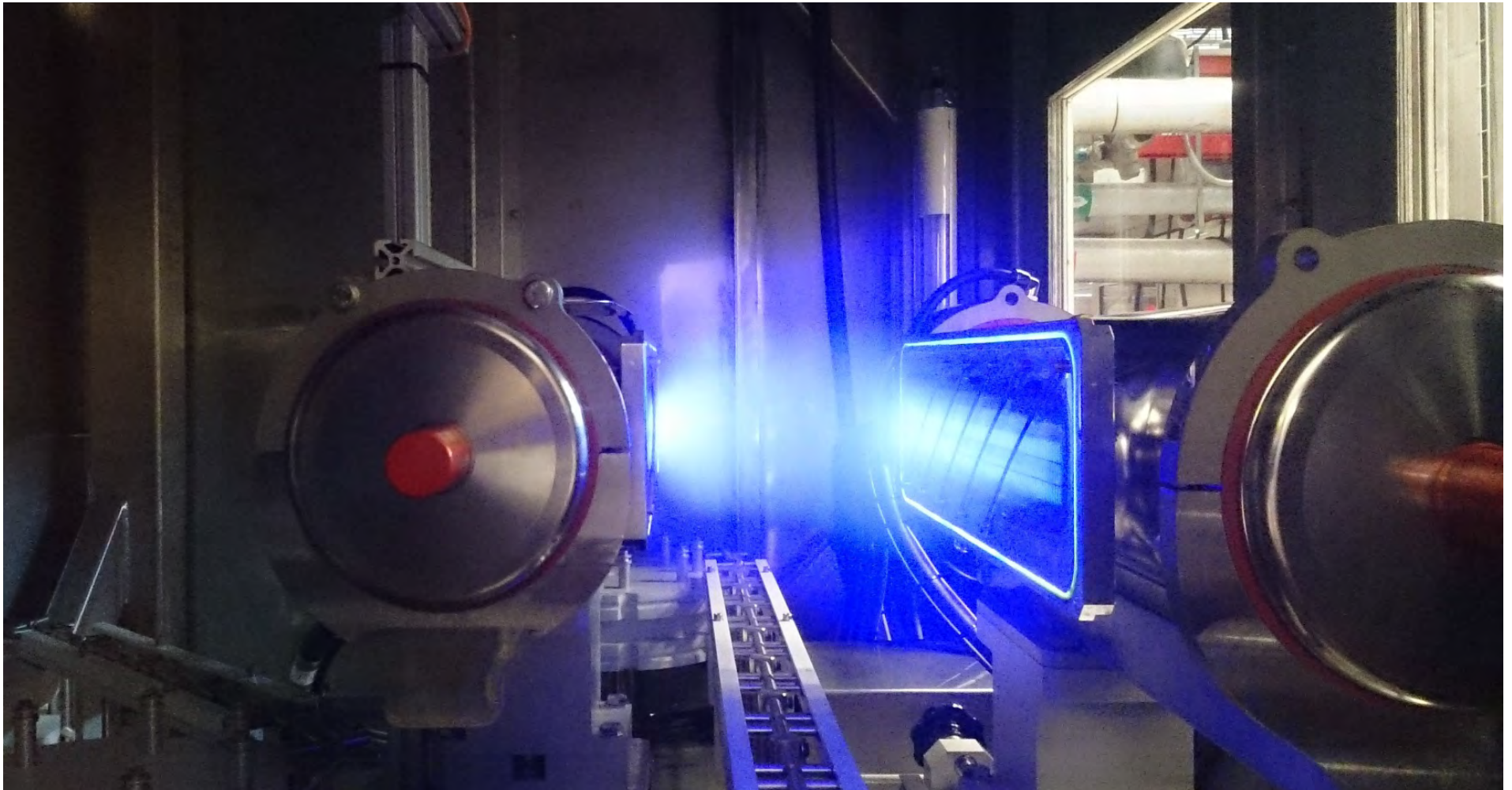
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EBLab, "Lamp" and "Brush"-Type



ebeam Technologies

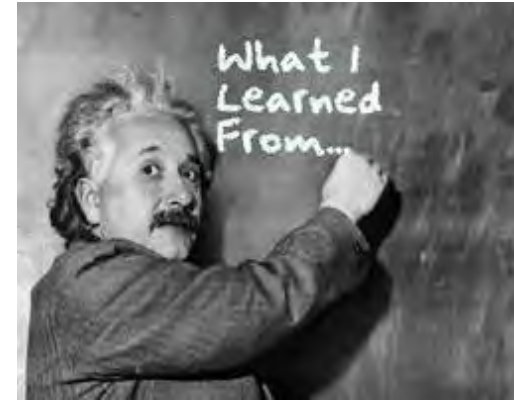
Lamps in crossfire arrangement in action



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Take Home Messages

- ebeam = electrons in atmosphere
 - non-vacuum = continuous processing (vs. batch)
- ebeam = electron shower
 - no writing, no location precision of electrons
 - high energy (> 80kV) means high spacial distribution
- ebeam = cold modification
 - low energy per surface area
- ebeam = tuneable depth
 - Depth only dependent on density and kinetic energy
 - depth can be changed with same device
- ebeam Innovation = sealed emitter
 - different business model
 - different maintenance model
 - changes CAPEX/OPEX model



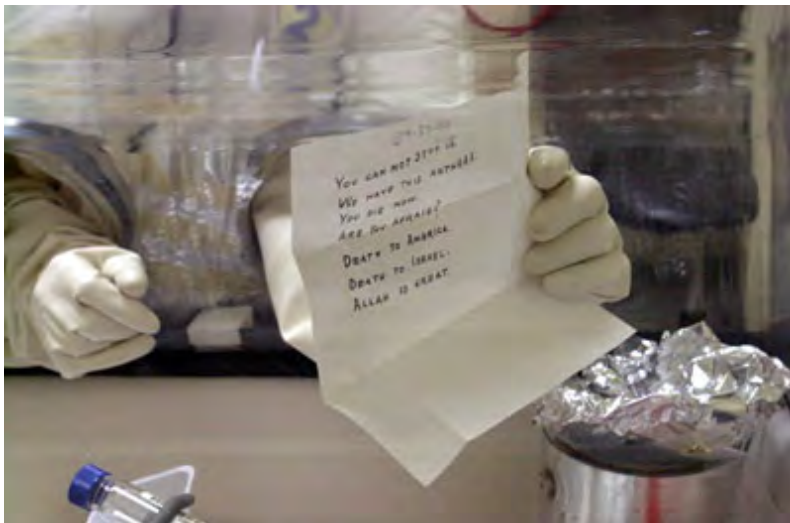
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EB for sterilization
—

ebeam



The Amerithrax Case (USA – 2001)

a case only EB could solve

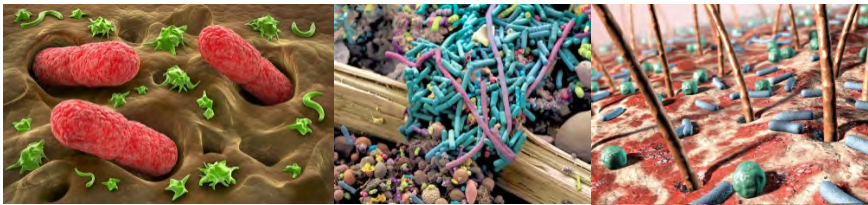


- Problem
 - Live Anthrax Bacteria mailed through USPS to different high profile politicians
 - 5 deaths, 17 non-fatal
- Solution
 - Government Mail was processed through EB to abate potential bio-warfare
- Differentiator
 - Only EB offered short turn-around-time needed

ebeam Technologies

Food & Feed-, Bio-, Medical-, Pharma- Technologies

Market Driver - Our Race against Pathogens



The matrix of pathogens in our ENVIRONMENT

- a. Livestock production
- b. Human medicine / multi resistance against antibiotics
- c. Environmental hygiene
- d. Global food/feed safety

→ some solutions BUT, NO real alternative

ebeam Technologies

Food & Feed-, Bio-, Medical-, Pharma- Technologies

4 markets, but **1** issue

BIOSAFETY

FOOD



ebeam

BIO



MED



PHARMA



Sterilization Comparison Matrix

	chemical		thermal	radiation				
	EO	Perox	Steam	Gamma	X-Ray	HE-ebeam	LE-ebeam	UV
Turn Around Time	-- long post treatment	++	O	-- Co60 varies over time, service center	O	- service center	+++	++
Goods heating	+++	+ drying	---	- long exposure	+ / ++ +	+ / ++ +	+**	++*
Energy	O	-	--	O (includes supply chain)	O	+++	+++	+
Penetration	+ Gas	- surface	O	+++	+++	+++	O energy dependent	- / ++ very surface if opaque
Chemicals	--- toxic gas	-- toxic chemical	+	+	+	+	+	+
Integration	--- highly toxic gas	-- highly corrosive liquid	-	--- / -- service provider only	-- high shielding requirement	--- service provider only	+ some shielding requirement	+++
log 8				OK	OK	OK	OK	HARD

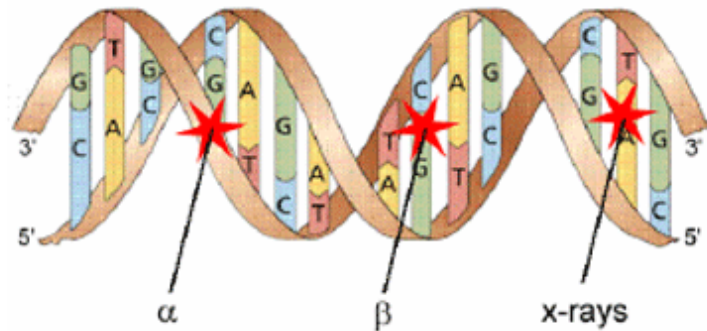


* has IR contribution without sterilizing effect

** 100% effect of energy deposited. High rate = high energy deposition.
no problem with chiller

Sterilization by Radiation

What happens

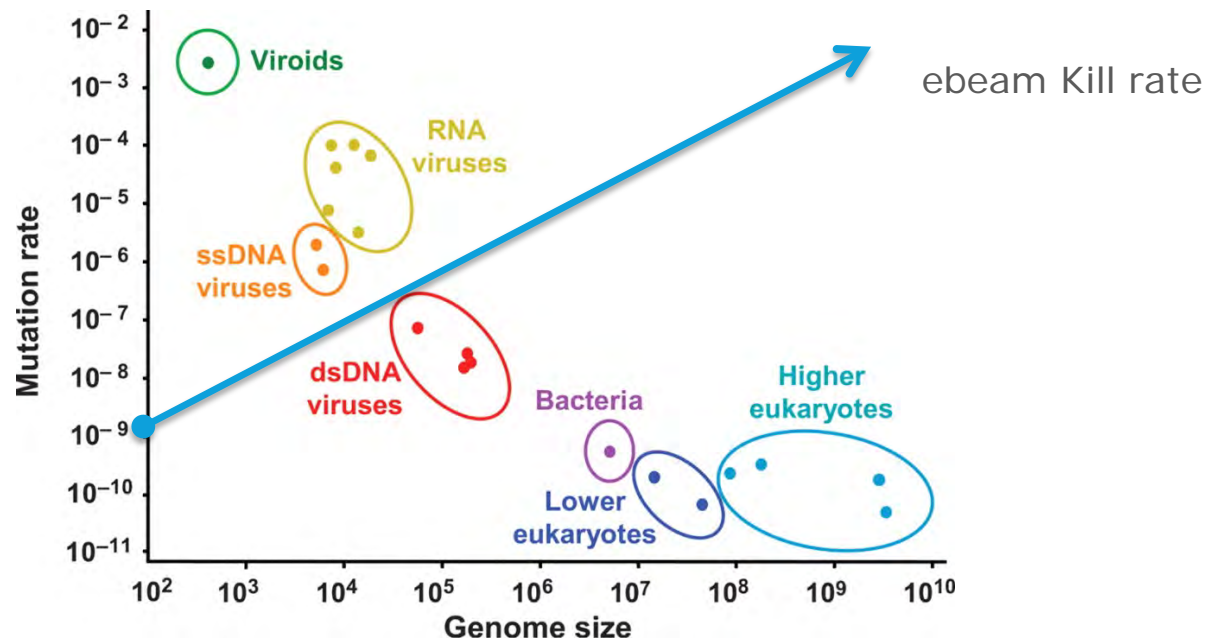


Direct action of ionizing radiation on DNA.

- α particle breaks the “sugar phosphate backbone” of the DNA
 - Difficult to repair and Killing the cell
- β particle breaks hydrogen bonds,
 - Difficult to repair killing or inactivates the cell
- γ / X-rays damage bases
 - Difficult to repair and inactivates the impairing the reproduction massively

Sterilization by Radiation

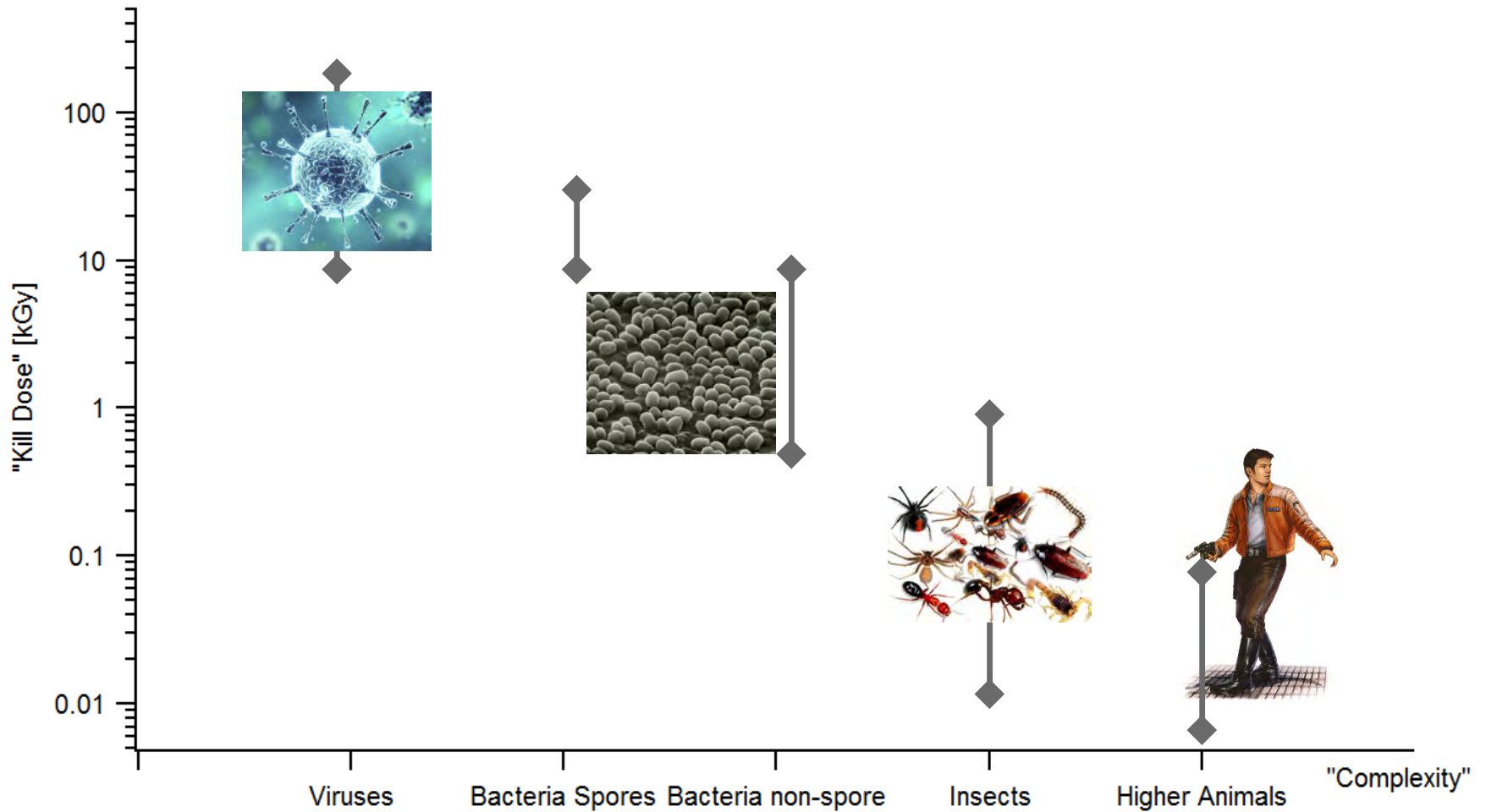
Bacteria versus virus : Complexity matters



- Killing/Inactivation is stronger with high DNA Content
- High liquid content creates more free radicals and leads to stronger inactivation

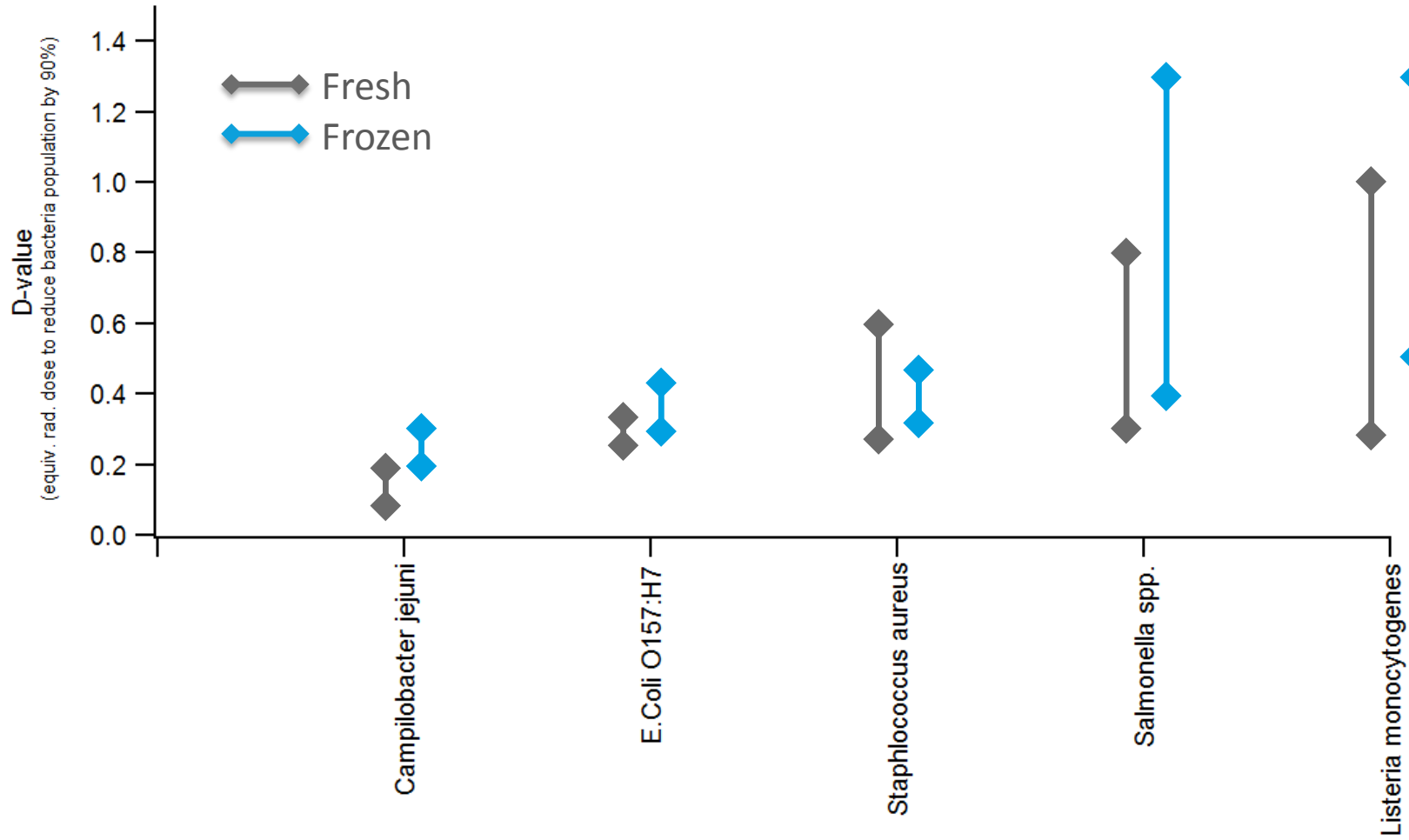
Sterilization by Radiation

needed Doses to kill various organisms



Typical irradiation

D-values of pathogens (matrix = meat)



Sterilization by radiation

Basics

Kill rates vary from microorganism to microorganism (1-3)

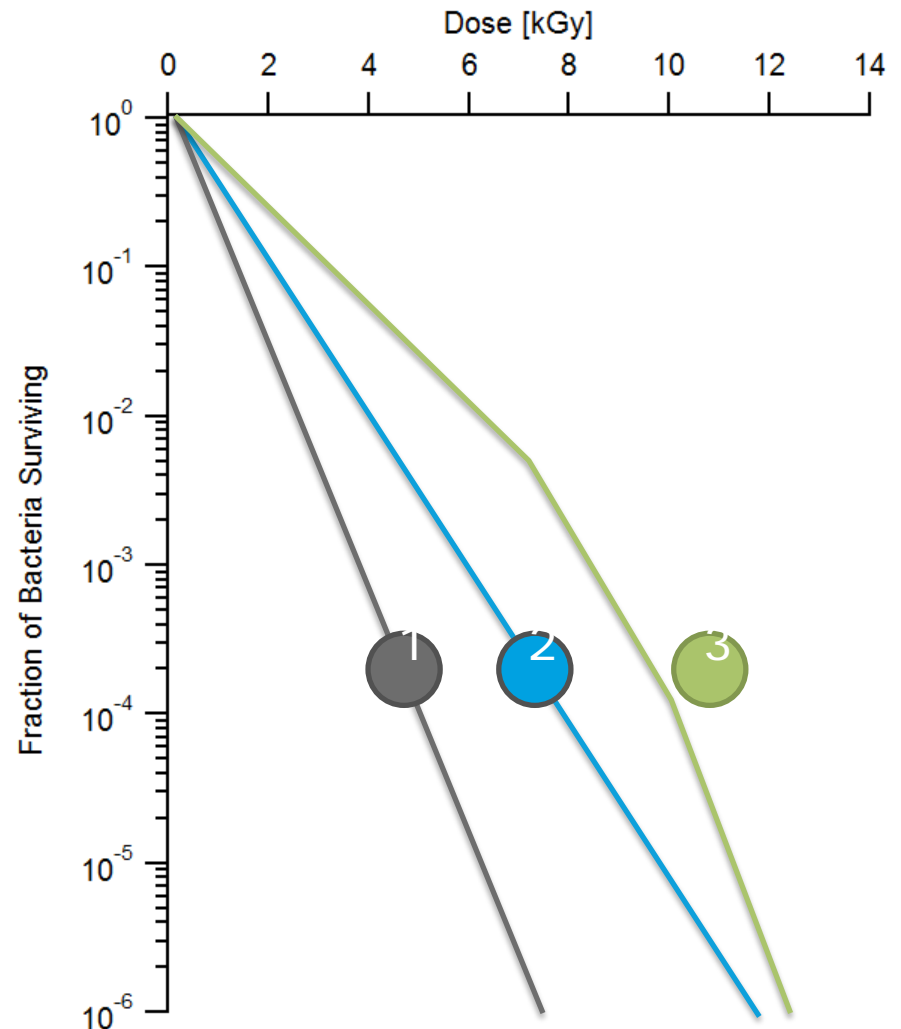
Example:

- D-Value = 2kGy → kills 9 out of 10 microorganism (blue curve)
- Bio burden: 100 microorganisms
- Required SAL (sterilisation assurance level) of 1E-6 (1 in a million chance one bacteria survived)

Required Dose

- 2 · 2kGy to decimate microorganisms to 1
- 6 · 2kGy to achieve SAL

Total required dose = 16kGy



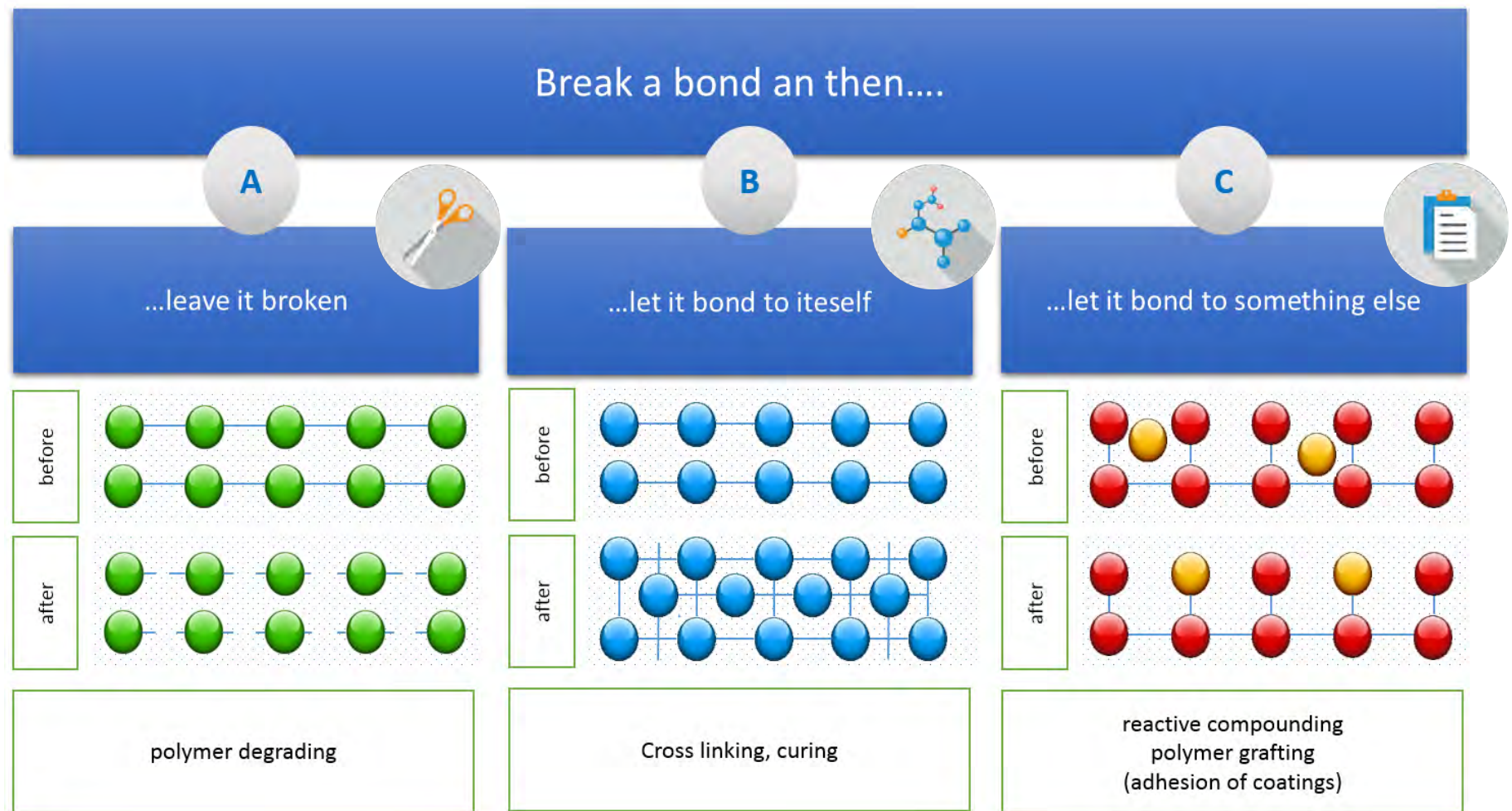
—
EB for inline
sterilization—
Examples
—

ebeam



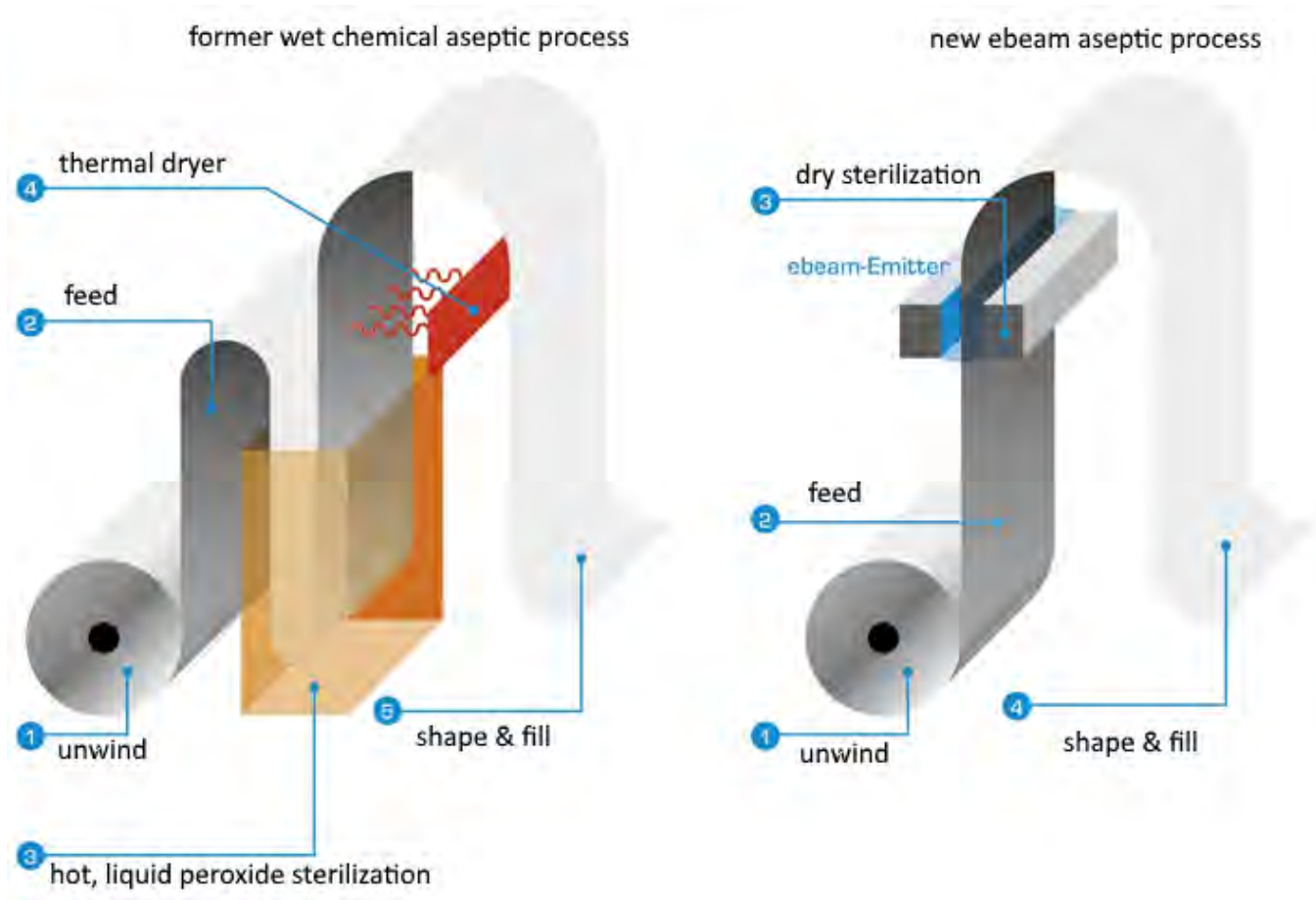
The ebeam essence

physical basic effects...



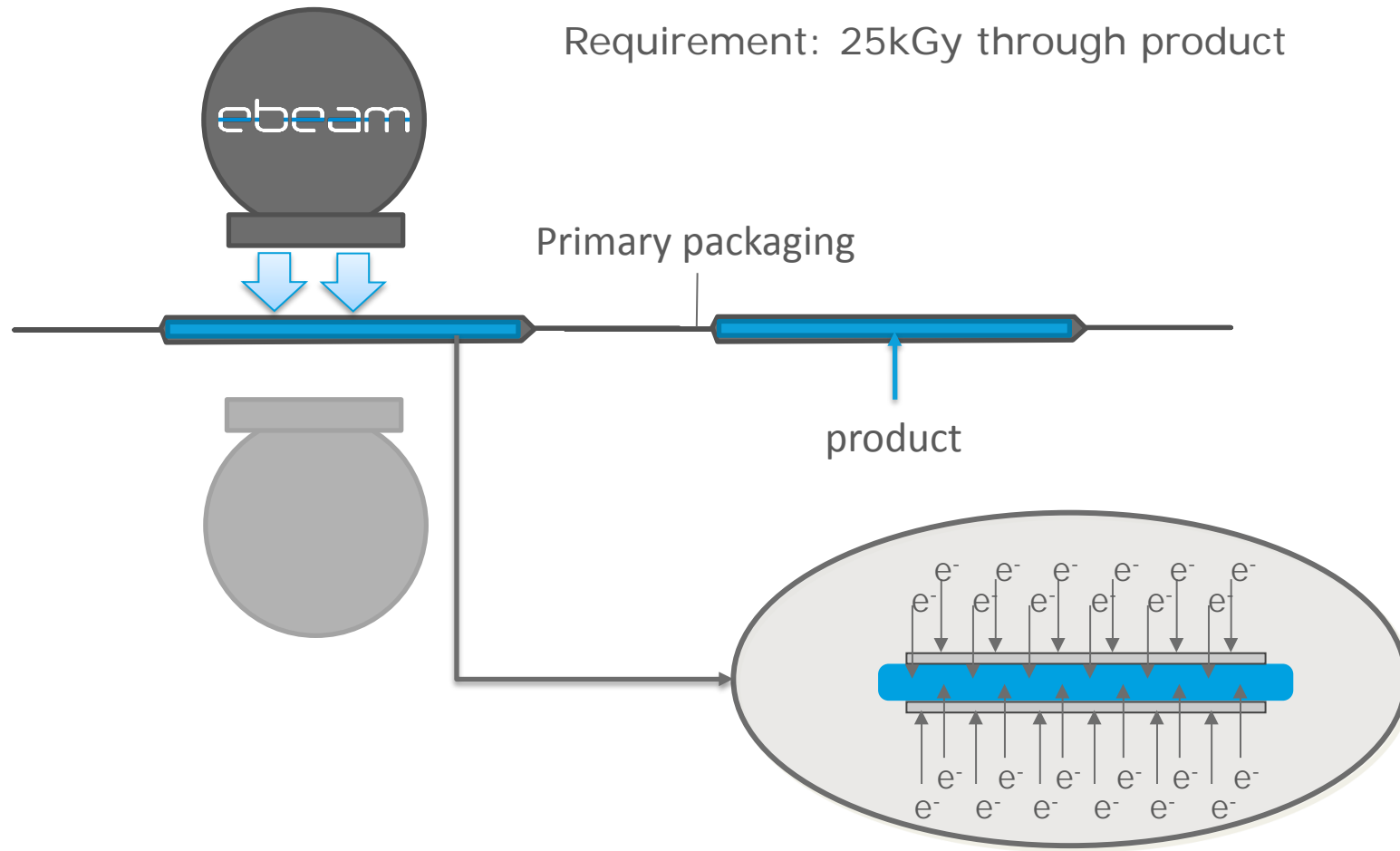
ebeam for the masses

Tetra Pak - chemical-free sterilization



Inline Sterilization Applications

Webbased in primary packaging

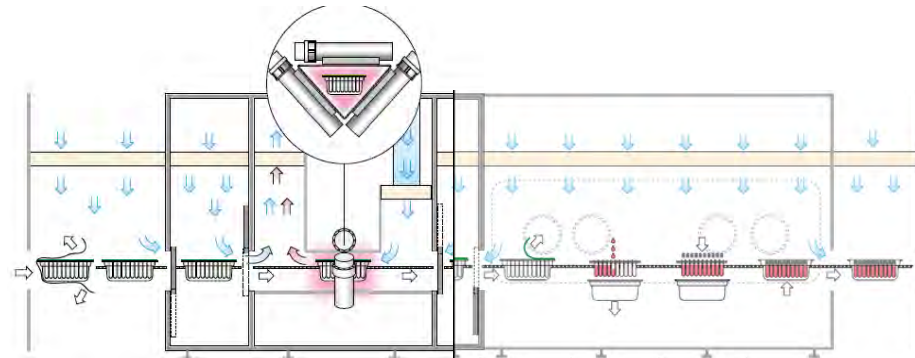


Inline Sterilization Applications

Pharma : Packaging Tubs, 3D surface sterilization



- **Presented by SKAN**
March 2014
- Sterilisation of **tubs for syringe filling lines**
- Substitutes hydrogen peroxide that has been in use for 40 years
- **Dry, non-contact**



Grafting / Functionalization

surface properties - wettability





Bread Shelflife

Situation:

- 20 % bread vasted
- Chemicals not allowed
- 30 % Longer shelf life required

Approach:

- Bread sterilizing (! Legislation !)
- Sterile foils

Solution:

- Active packaging !
- Beaming antimicrobiol and scavenger coating on the foil



- ✔ Anti-microbial sorbic acid based films can be used for bakery products and have commercial potential
- ✔ The effective concentrations of sorbic acid normally do not alter the taste or odour of food product and they are also considered harmless [1]

[1] Markarian, J., *Consumer demands push growth in additives for active packaging*. *Plastics, Additives and Compounding*, 2006. **8**(5): p. 30-33.



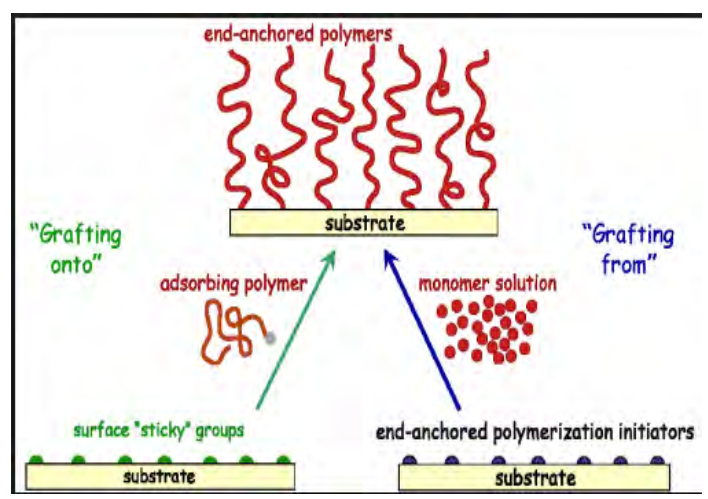
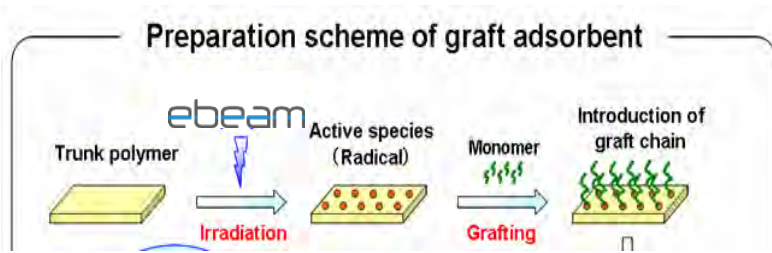
Solution

Grafting of pack material

Active packaging with Grafting:

- Releasing
- Emitting
- Removing

- O₂ a.o. Scavengers
- Antimicrobiol agents



—
Summary
—



Summary
the EB (r)evolution



What happens if size makes all the difference?

ebeam
blue is the new green

think **BIG!**

THANK YOU



Contact details



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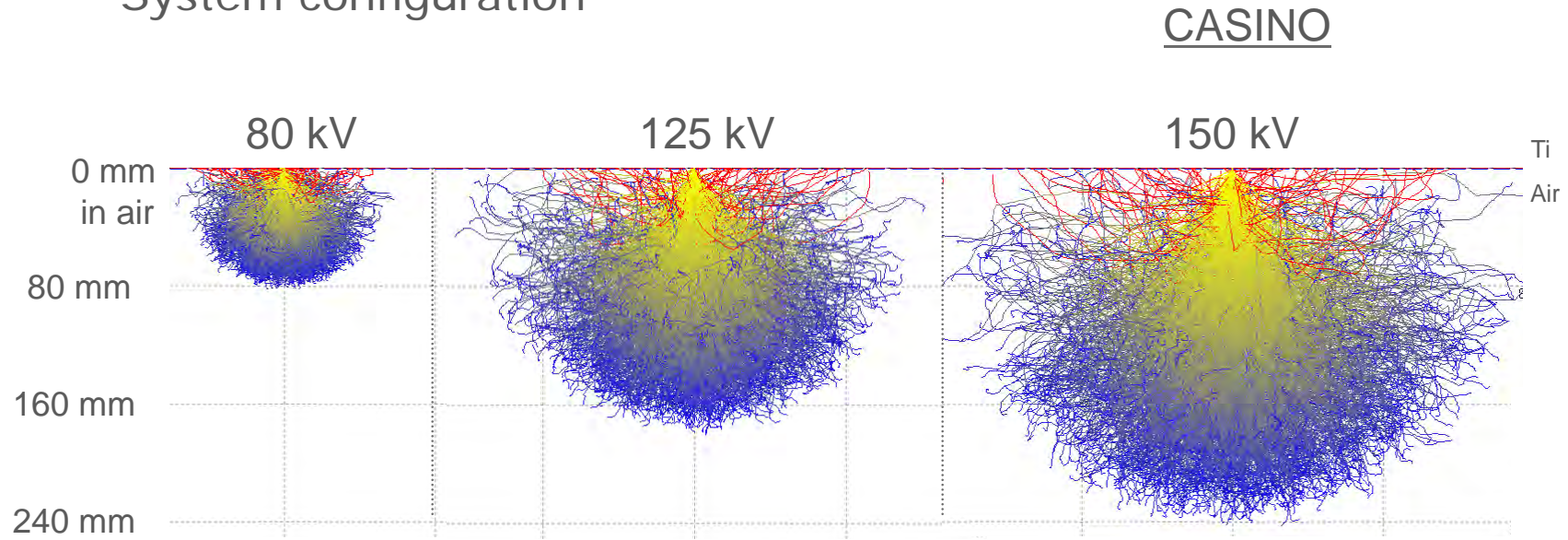
COMET AG - ebeam Technologies
Ian Bland
VP Business Development
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ian.bland@comet.ch



Energy Delivery: Photons vs. Particles

Electron Scattering

- The distribution of energy absorbed by a material depends upon:
 - Energy of electron
 - Atomic number and density of materials
 - System configuration

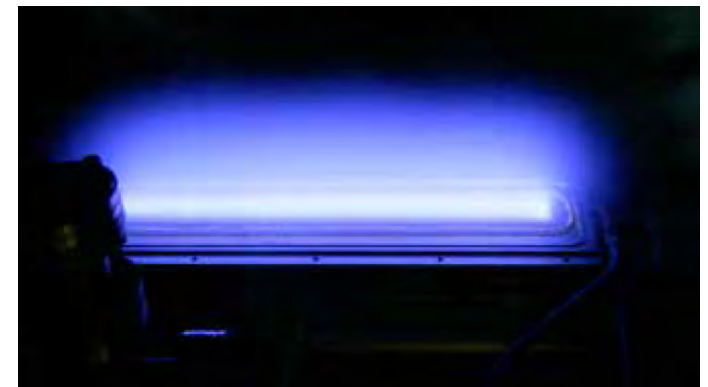
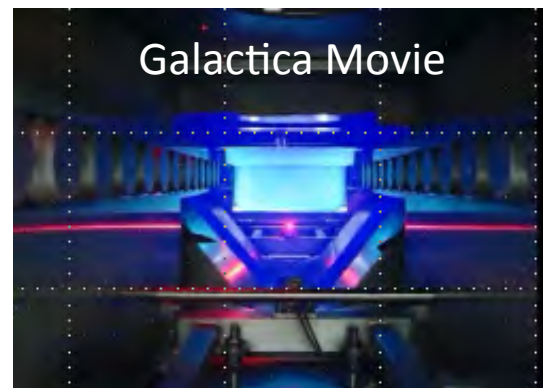
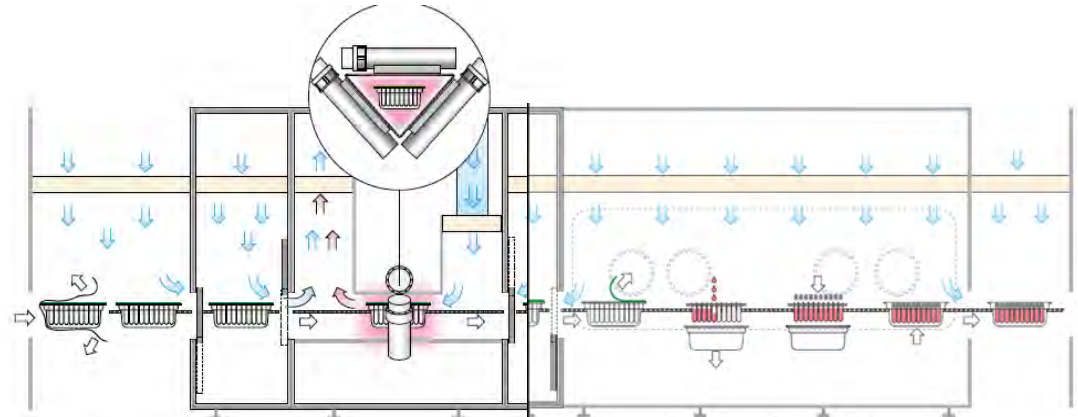


Monte Carlo simulation of point source EB scatter

Sterilization

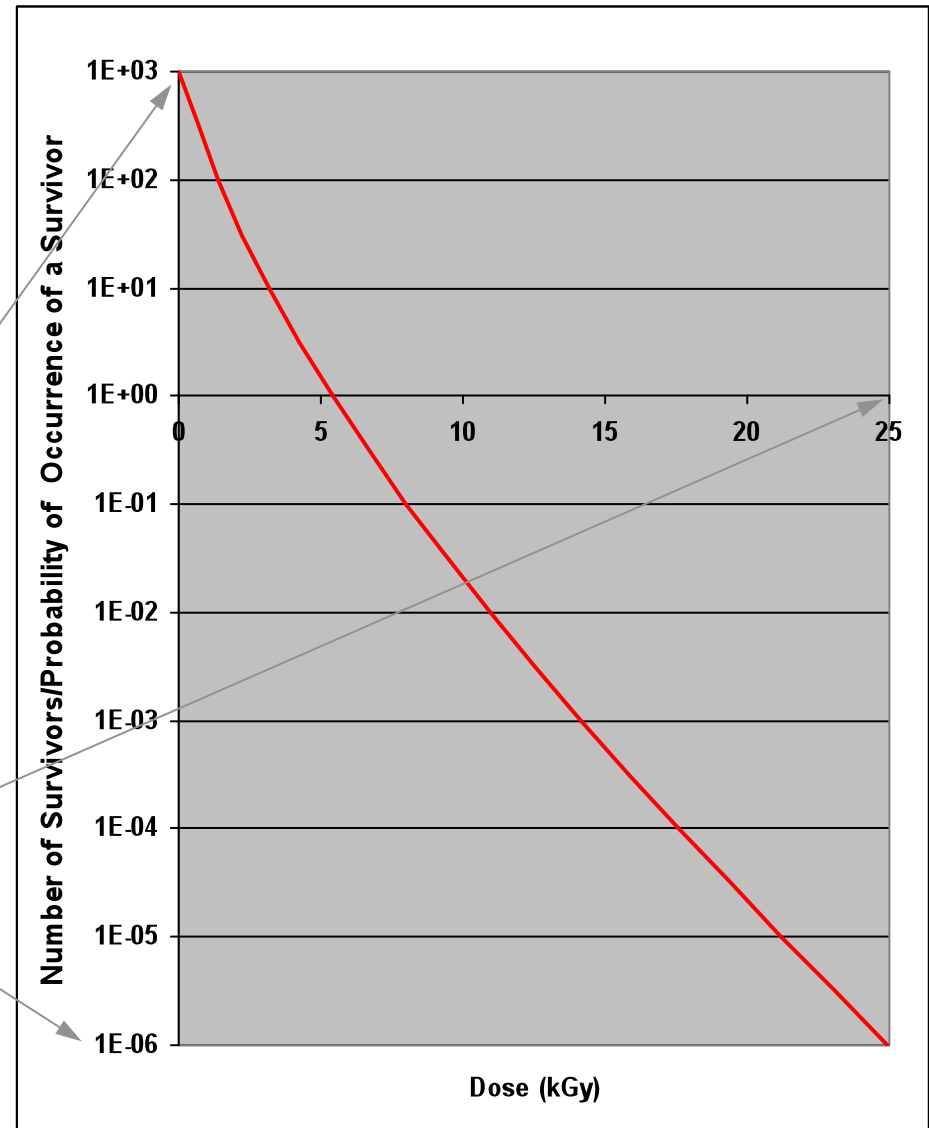
Pharma : Packaging Tubs, 3D surface sterilization

- **Presented by SKAN**
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- Substitutes hydrogen peroxide that has been in use for 40 years
- **Dry, non-contact**



Sterilisation Basics (2)

- Standard for medical industry:
EN ISO 11137-1 and 2
- EN ISO 11137 uses a standard distribution of resistances of bacteria
- Example:
 - **Bio burden: 1'000 microorganisms**
 - **Required SAL 1E-6**
 - **Required Dose 25kGy**

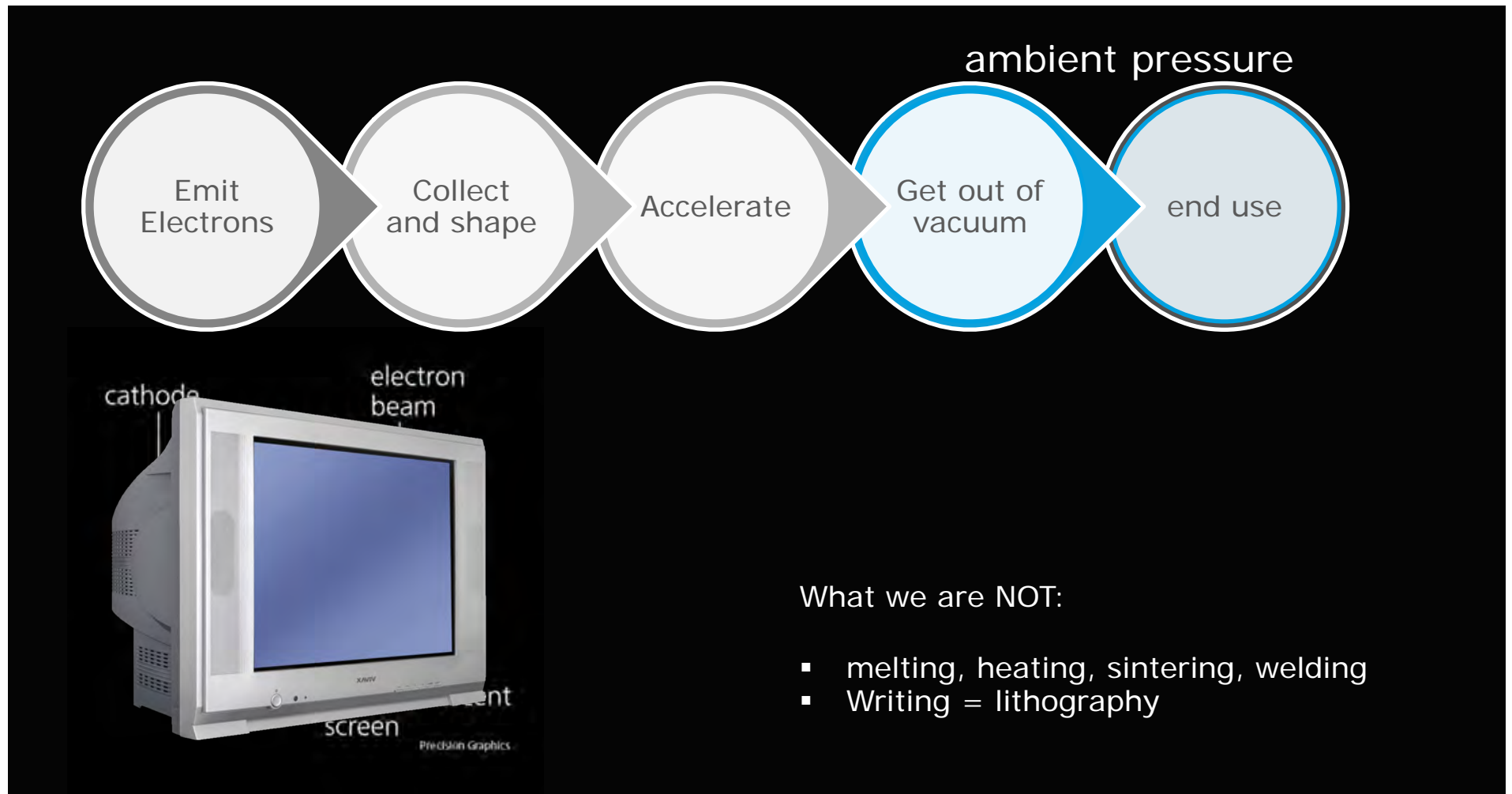


Factors affecting irradiation effectiveness *against microorganisms in foods or food packaging*

- Growth phase of microorganism
- Type of matrix; for e.g. food (lean vs fat)
- Moisture content (water level)
- Temperature of matrix; for e.g. food (frozen vs heated)
- Presence of oxygen (aerobic vs anaerobic)

(Atmospheric) Electron Beam

What is it?



(Atmospheric) Electron Beam *High Voltage Accelerators, Scanning*

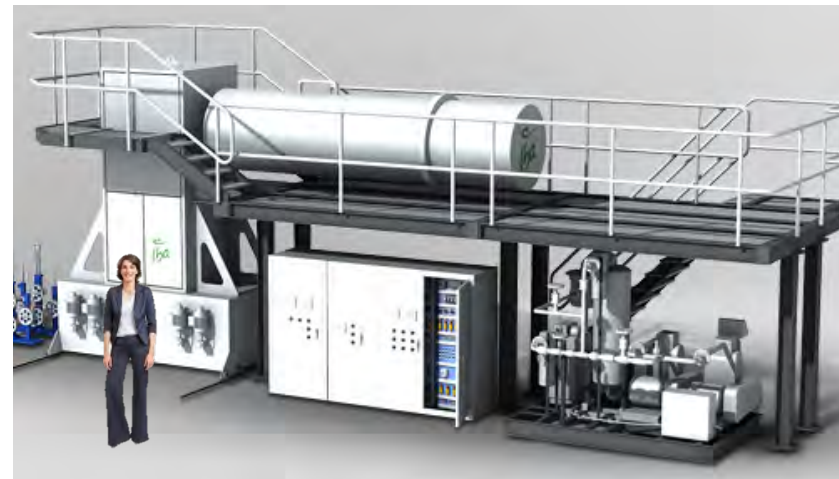
EB in Bunker : 1 MeV – 9 MeV



- Service Centers & High Volume Clients
- Very expensive (Infrastructure and Beam)
- Not for thin web-based products

ebeam

«Self-shielded» : 500keV-1 MeV



- Service Centers & High Volume Clients
- Mainly Cable&Wire and Tire
- Expensive (Infrastructure and Beam)
- Not for thin web-based products

(Atmospheric) Electron Beam

Low Energy EB (flood beams) & the the "e-light bulb"

«Self-shielded» : 80-300keV



Wide Web, pumped Systems

- pumped
- hermetically sealed
- Wide-web for thin, web-based products

ebeam

«Sealed & Self-shielded» : 80-300keV

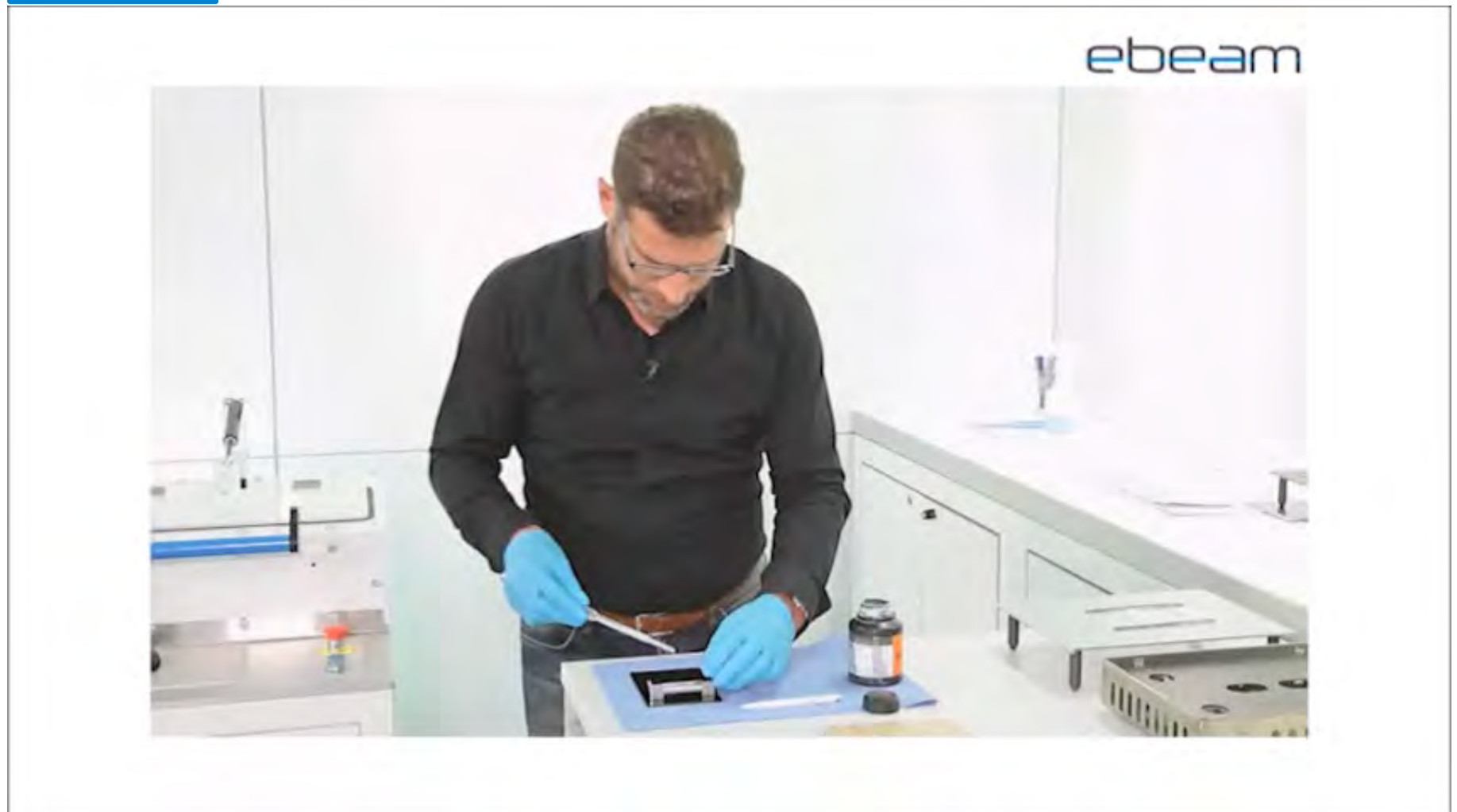


the ebeam «light bulb»

- small
- affordable
- hermetically sealed
- Narrow-web for thin, web-based products
- replacements within minutes

EB for the masses

Ink development on the EBLab



ebeam

https://www.youtube.com/watch?v=EfTC_4t1_Y8

5/18/16 | 48

EB Systems (Broadbeam and ebeam systems)

The EB power house

PCT CE-Series (ebeam)



PCT LE-Series (Broadbeam)



PCT EP-Series (Broadbeam)



Energy	80-200kV	90-175kV	125-300kV
Width*	0.25m / 0.40m	0.9m / 1.37m / 1.8m / 2.75m	up to 3.3m
Speed	100m/min (30kGy)	400m/min (30kGy)	400m/min (30kGy)



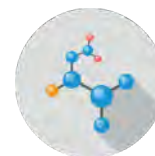
EB Example (EVA)
EB crosslinking (EBXL)



different Dose

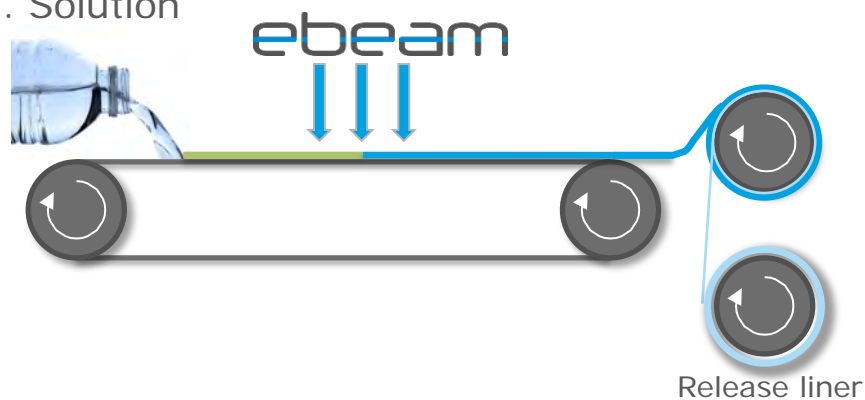
Oven
90°C





Curing *Hydrogel wound dressing*

PVA aq. Solution



- Continuous production
- High purity
- High mechanical strength
- Controlled release of drugs



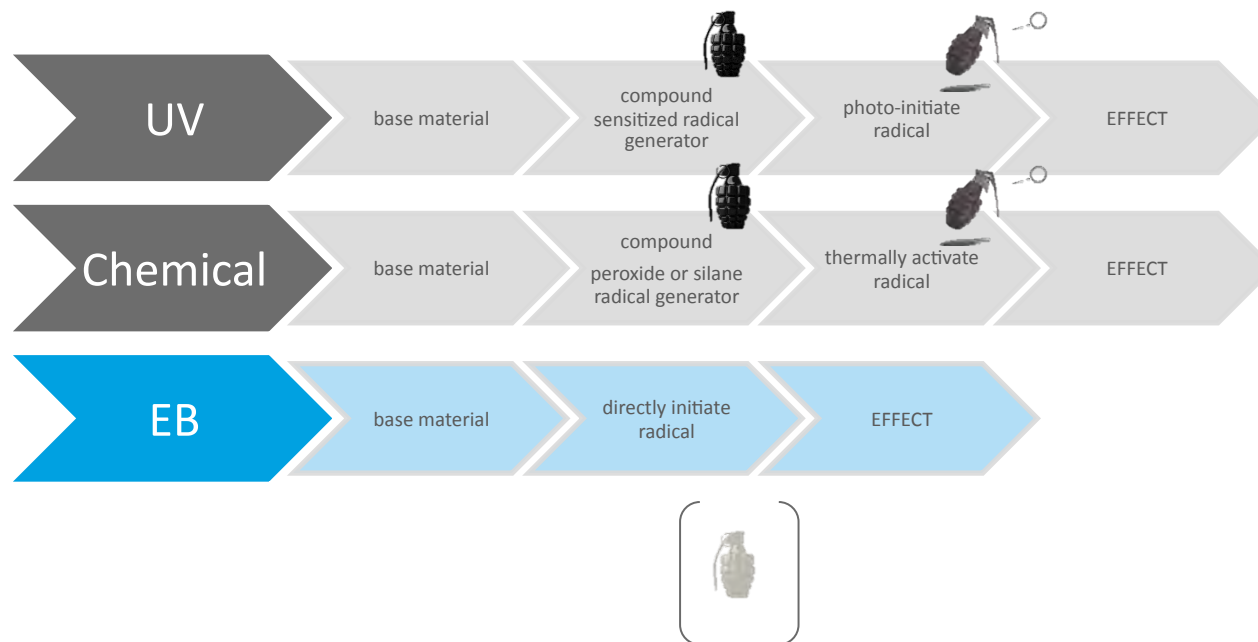
COMET

global presence with 12 locations



Radicals are the ways to initiate change

What are the differences?



EB formulations

- No solvents (wet = dry thickness) ⇒ No VOC
- No Photoinitiator = Odour and Migration advantages
- Low heat = works with very thin material