Food Hygiene Biocides: Regulations & Reality

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SfAM/NBIC Microbes and Biofilms in the Food Industry

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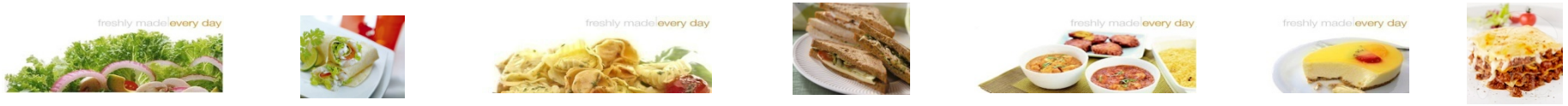
Food Hygiene Biocides Assure Food Hygiene & Protect Public Health

Used worldwide in disinfectants and sanitisers in households, professional food producers, in foodservice and at retail

Legal and supported in the Biocidal Products Regulation (528/2012)

Regulation (EC) No 396/2005 (pesticides maximum residue levels) ~~does~~ did not consider food hygiene assurance uses (until we came along)…

What Are Chilled Foods?



Chilled Prepared Foods

- Entrées (some RTE)
- Dressed salads
- Leafy salads
- Prepared vegetables
- Prepared fruit
- Delicatessen products
- Sandwiches, rolls & wraps
- Sandwich fillings
- Savoury pastries & quiches
- Recipe dishes/kits (ready meals)
- Dips & dressings
- Stir fry kits
- Pizza
- Meal centres
- Meal Accompaniments
- Sushi
- Filled and plain fresh Pasta
- Soups (some RTE)
- Sauces (some RTE)
- Desserts

Items in green = ready to eat (RTE)

EU Microbiological Criteria Rules for *L. monocytogenes* (2073/2005 apply)

Listeria monocytogenes (Lm)

- One of 20 *Listeria* species
- **Lm is the only species legislated for – human pathogen**
- Widespread in environment: soil, water, animal faeces, vegetation
- Carried by ≤10% of people
- Long incubation period: up to 90 days before symptoms appear

- Grows at refrigerator temperatures (-1.4°C minimum)
- Survives freezing (-18°C)
- Relatively heat resistant (70°C/2 mins for 6-log reduction)
- Grows in low O_2 environments, e.g. vacuum packed foods
- Highly salt tolerant (Min A_W 0.92): survives and grows even in cured foods
- Min pH for growth 4.2-4.3

- **Forms persistent biofilms on surfaces**
  - **Resistant to cleaning and disinfection**
  - **Creates reservoir of contamination**
  - **Must enforce rigorous hygiene schedules to manage**

Major transmission route into humans is through contaminated foodstuffs

- Vulnerable groups are particularly susceptible
- Transmission from infected food, the environment, mother to foetus
- **Main cause of death from foodborne illness in the EU**

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Biofilms

Robust hygiene systems

- Clean and disinfect – validate and monitor
- Guidance: www.chilledfood.org/FBIG

Multi-species biofilms: how to avoid unfriendly neighbors Renduelles & Ghigo: http://dx.doi.org/10.1111/j.1574-6976.2012.00328.x 972-989

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2018 European Top 5 Foodborne Diseases Morbidity & Mortality

Disease		Hospitalisations				Deaths				
	No. confirmed human cases	Status available (%)	Number of reporting ‡countries	Reported hospitalised cases	Proportion hospitalised (%)	Outcome available (%)	No. reporting MS	Reported Deaths	Case Fatality (%)	Fatality Rate cf Lm
Campylobacteriosis	246,571	27.7	18	20,848	30.6	72.7	16	60	0.03	520
Salmonellosis	91,857	43.2	15	16,556	41.7	67.0	17	119	0.19	82
STEC infections	8,161	37.3	18	1,151	37.8	60.4	20	11	0.22	71
Yersiniosis	6,699	26.4	14	519	29.3	56.8	15	3	0.08	195
Listeriosis	2,549	42.4	17	1,049	97.0	57.6	19	229	15.6	

*** 2017: Listeriosis date rate 345x Campylobacteriosis, 28x STEC**
**** 2016: Listeriosis death rate 540x Campylobacteriosis, 60x STEC**
*****2015: Listeriosis death rate 590x Campylobacteriosis, 74x STEC**

EFSA/ECDC, 2019. EU One Health Zoonoses Report 2018. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5926

* EFSA, ECDC, 2018. EU summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2017. http://ecdc.europa.eu/sites/portal/files/documents/zoonoses-%20food-borne-outbreaks-surveillance-2017.pdf
**EFSA, ECDC, 2017. EU summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2016. EFSA Journal, 10.2903/j.efsa.2017.5077
*** EFSA, ECDC, 2016. EU summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2015. EFSA Journal, 10.2903/j.efsa.2016.4634

Comparing European Countries' Listeriosis Rates 2014-18

All rates per 100k population

Sentinel systems:

Belgium: 2015-18 covers 80% population
Spain: 2015-17 no coverage info

Non-EU rates:
South Africa: 1.84 (2017-18)
USA: 0.3
Australia : 0.3*
NZ: 0.6

* incomplete data

US rate data:
https://www.cdc.gov/listeria/technical.html

Australia:
https://www2.health.vic.gov.au/public-health/infectious-diseases/disease-information-advice/listeriosis

NZ:
https://www.foodstandards.gov.au/publications/Documents/Listeria%20monocytogenes.pdf

2014	Cases	Rate
Italy	52	-
Portugal	-	-
Denmark	92	1.64
Sweden	125	1.30
Iceland	4	1.23
Switzerland + Liechtenstein	98	1.20
Finland	65	1.19
Spain	161	1.15
Luxembourg	5	0.91
Slovenia	18	0.87
Belgium	84	0.75
Germany	597	0.74
Austria	49	0.58
France	374	0.57
Norway	29	0.57
Netherlands	90	0.54
Slovakia	29	0.54
EU	2,161	0.52
Hungary	39	0.40
Czech Rep	38	0.36
Ireland	15	0.33
UK	201	0.31
Lithuania	7	0.24
Malta	1	0.24
Poland	86	0.23
Latvia	3	0.15
Bulgaria	10	0.14
Greece	10	0.09
Croatia	4	0.09
Estonia	1	0.08
Romania	5	0.03
Cyprus	0	0.00

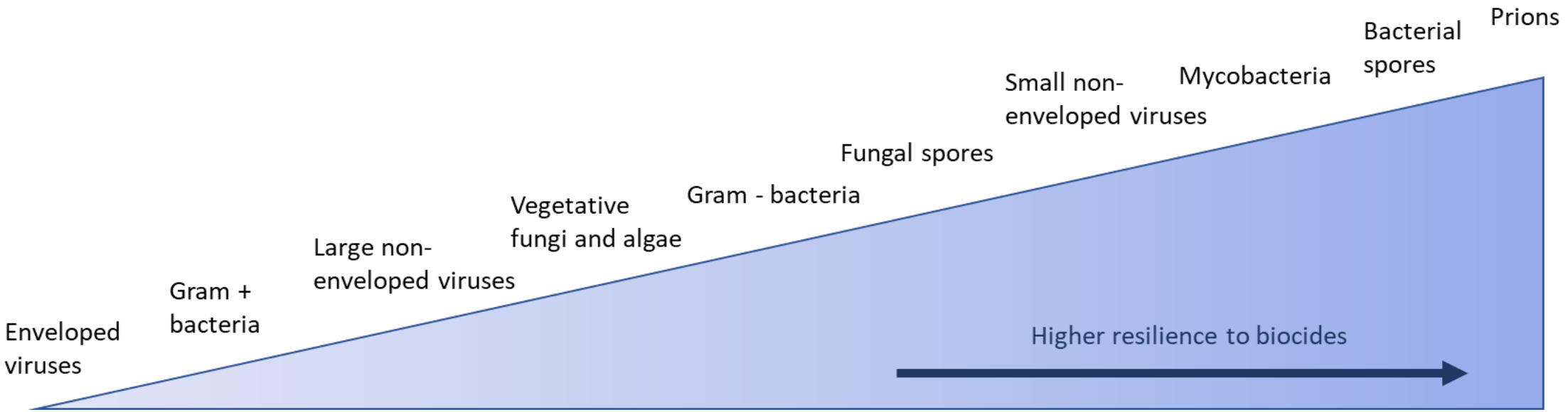
2015	Cases	Rate
Spain	206	0.99
Malta	4	0.93
Sweden	88	0.90
Finland	46	0.84
Estonia	11	0.84
Denmark	44	0.78
Belgium	83	0.74
Germany	580	0.71
Switzerland + Liechtenstein	54	0.65
Slovenia	13	0.63
France	412	0.62
EU	2,206	0.46
Austria	38	0.44
Netherlands	71	0.42
Ireland	19	0.41
Latvia	8	0.40
Hungary	37	0.38
Norway	18	0.35
Czech Rep	36	0.34
Slovakia	18	0.33
UK	186	0.29
Greece	31	0.29
Portugal	28	0.27
Italy	153	0.25
Poland	70	0.18
Lithuania	5	0.17
Bulgaria	5	0.07
Romania	12	0.06
Croatia	2	0.05
Cyprus	0	0
Luxembourg	0	0
Iceland	0	0

2016	Cases	Rate
Spain	362	–
Finland	67	1.22
Belgium	104	0.92
Germany	697	0.85
Slovenia	15	0.73
Denmark	40	0.7
Sweden	68	0.69
Estonia	9	0.68
Switzerland + Liechtenstein	50	0.6
France	375	0.56
Austria	46	0.53
Netherlands	89	0.52
EU	2,536	0.47
Czech Rep	47	0.45
Norway	19	0.37
Lithuania	10	0.35
Luxembourg	2	0.35
UK	201	0.31
Italy	179	0.3
Latvia	6	0.3
Portugal	31	0.3
Ireland	13	0.28
Poland	101	0.27
Hungary	25	0.25
Malta	1	0.23
Greece	20	0.19
Slovakia	10	0.18
Croatia	4	0.1
Bulgaria	5	0.07
Romania	9	0.05
Cyprus	0	0
Iceland	0	0

2017	Cases	Rate
Spain	284	–
Iceland	6	1.77
Finland	89	1.62
Denmark	58	1.01
Germany	726	0.88
Luxembourg	5	0.85
Sweden	81	0.81
Belgium	73	0.80
Netherlands	108	0.63
Slovenia	13	0.63
France	370	0.55
Switzerland	45	0.53
EU Total	2,480	0.48
Portugal	42	0.41
Hungary	36	0.37
Austria	32	0.36
Lithuania	9	0.32
Poland	116	0.31
Estonia	4	0.30
Norway	16	0.30
Ireland	14	0.29
Czech Rep	30	0.28
Italy	164	0.27
UK	160	0.24
Slovakia	12	0.22
Croatia	8	0.19
Greece	20	0.19
Bulgaria	13	0.18
Latvia	3	0.15
Romania	10	0.05
Cyprus	0	0.00
Malta	0	0.00

2018	Cases	Rate
Estonia	27	2.05
Finland	80	1.45
Spain	370	0.89
Sweden	89	0.88
Denmark	49	0.85
Luxembourg	5	0.83
Germany	683	0.82
Belgium	74	0.81
Latvia	15	0.78
Lithuania	20	0.71
Portugal	64	0.62
Switzerland	52	0.61
Iceland	2	0.57
France	338	0.51
Slovenia	10	0.48
EU Total	2,549	0.47
Norway	24	0.45
Ireland	21	0.43
Netherlands	69	0.40
Poland	128	0.34
Austria	27	0.31
Slovakia	17	0.31
Czech Republic	31	0.29
Italy	178	0.29
Hungary	24	0.25
UK	168	0.25
Malta	1	0.21
Greece	19	0.18
Romania	28	0.14
Bulgaria	9	0.13
Cyprus	1	0.12
Croatia	4	0.10

Susceptibility of Different Microorganisms to Biocides



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Efficacies of Food Hygiene Biocides against *Listeria monocytogenes*

Sanitiser type	In absence of protein residues (effective cleaning)				In presence of protein residues (poor cleaning)			
	No. studies reviewed	No. observations	Total no. replicates	Lm Mean reduction (log cfu)	No. studies reviewed	No. observations	Total no. replicates	Lm Mean reduction (log cfu)
Halogen	3	27	124	3.8	2	9	60	2.4
Hypochlorite	11	321	891	5.5	4	38	117	2.8
Peracetic acid	6	177	484	4.6	2	24	52	3.8
*Quaternary ammonium	5	59	262	6.1	2	8	56	5.3

Adapted from: http://safesmokedfish.foodstandards.gov.scot/assessment/5130

*** Classed as Plant Protection Product by EU and regulated as such, i.e. MRL set**

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Cleaning (& Disinfection)

- **Ensuring food production environment cleanliness is a fundamental requirement of food hygiene legislation (and a Critical Control Point)**

- **EC General Food Hygiene Regulation 852/2004:**

  - Chapter V, 1: *All articles, fittings and equipment with which food comes into contact are to: (a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination…*

  - HACCP principles – Art 5: establish, validate and monitor efficacy of cleaning and disinfection (CCP)

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Comparing Lm Prevalence in RTE Foods

- **UK surveys - higher prevalence in:**
  - Food sliced to order (e.g. delicatessens) *cf* pre-packed retail
  - Loose (non-prepacked) foods without clear storage/usage instructions
  - Food from sandwich bars, butchers, convenience shops, bakeries, i.e. produced & sold by smaller businesses
  - **Foods produced by businesses with less well developed hygiene systems resulting in reduced protection from re- or cross-contamination**

	*Mar–Sep 2007 (FSA B18024)	Apr 2012-Mar 2013 (FSA FS241042)	HPA/LACORS Survey May 2006-April 2007	
	Cooked sliced meat sold by **SMEs & major retailers	Cooked sliced meat sold by SMEs	Supermarket pre-packed	Sandwich bar
Lm	1.5%	3.8%	1.4%	5.7%

*** 2/3 of ~1600 samples from major retailers** ****SMEs = small and medium-sized enterprises**

13088 food samples from EU		Lm prevalence	>100/g
Fish	'At point of sampling'	10.40%	1.00%
Fish	End of shelf-life	10.30%	1.70%
Meat	End of shelf-life	2.07%	0.43%
Cheese	End of shelf-life	0.47%	0.06%

EFSA Journal 2013;11(6):3241

What Good Control Looks Like:
UK Chilled Food Industry Lm Data (2008-2019)

- **RTE food prevalence (909054 samples):**
  - ~0.7% Lm at any point during shelf life, of which
  - 0.0002% present at quantifiable levels, i.e. >20 cfu/g LOQ
- **Production environment prevalence (1592459 samples):**
  - Food contact surfaces <0.4% Lm (~774k samples)
  - Non-Food contact surfaces ~2% Lm (~818k samples)

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Food Hygiene Biocides Regulation

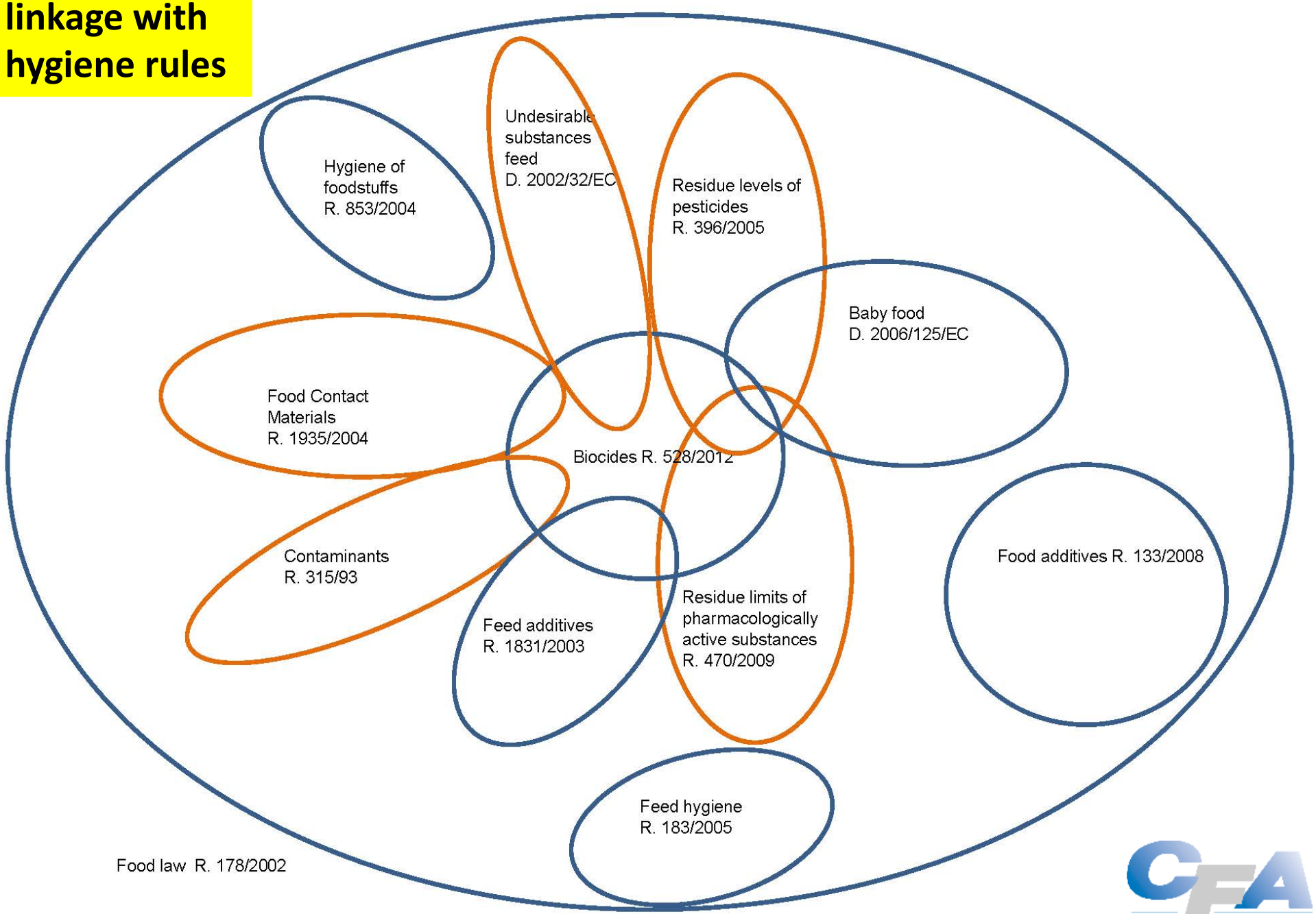
And what *we've done about it

*

Food & Biocides Industry Group
(www.chilledfood.org/FBIG)
~20 trade & professional organisations
from farm to fork, led by CFA

*

Until 2016 no linkage with hygiene rules



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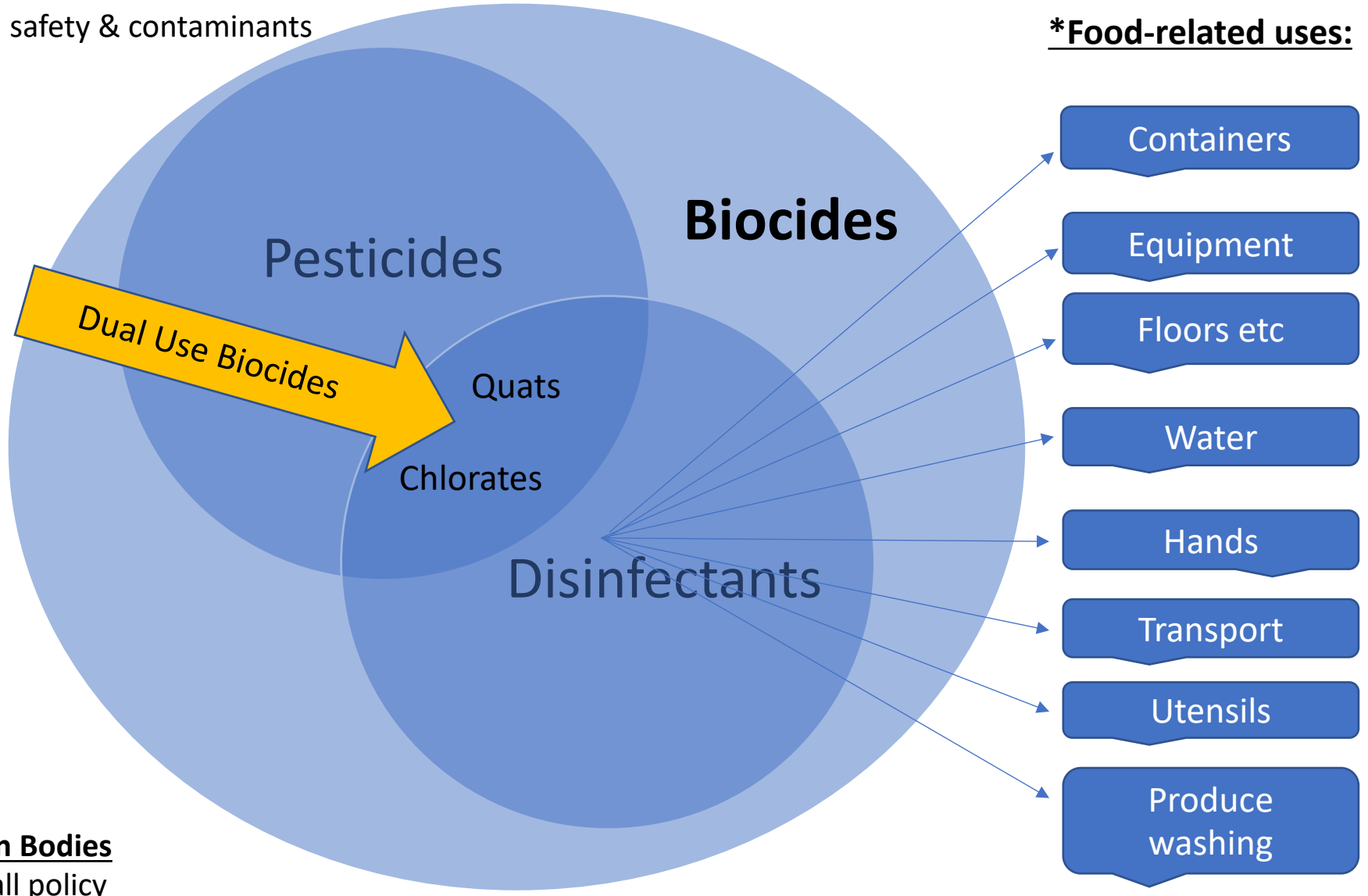
UK Government Roles

Local Authorities: hygiene enforcement (no role with biocides)
HSE: biocides inc biocides enforcement
FSA: food safety & contaminants



European Bodies

EC: overall policy
EU Chemicals Agency (ECHA): Biocidal Products Reg
EU Food Safety Authority (EFSA): food & biocides safety

* Primary production manufacture, foodservice, hospital catering, retail

Pesticides vs Other Biocides

- **Terminology:**
  - **Residues result from intentional addition of the regulated active to a food material - regulated**
  - **Traces result from unintentional carryover from legitimate use - reality**
- **Dual use biocides:**
  - Why apply Plant Protection Products (PPP) law to materials used to assure hygiene?
  - If material ever been used anywhere as a pesticide then MRL will apply
  - 0.01mg/kg default MRL (LOD)
  - Multicomponent/processed products not listed in legislation Annex (PPP law 396/2005) but EU and UK says are within scope

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Chlorate

- **Chlorate banned as PPP by EU in 2005**
- **BUT arises primarily from hygiene biocides inc mains water… and is heat stable**

- **Industry data gathering and lobbying since 2012 to achieve workable regulation reflecting the need to protect food hygiene and safety, and public health overall**

- **Cranfield report for DWI (Oct 2019) found:**
  - Chlorate present up to 0.5 mg/kg in water from high risk water treatment works
  - Level is dependent on:
    - Season (highest June-Sept – *E coli* mitigation)
    - Chlorination method (*OSEC & NaOCl highest risk)
    - Storage tanks' cleaning frequency

- **No legislated EU/UK chlorate maximum in drinking water – until DWD published 23/12/20**
  - EU Drinking Water Directive will set max levels (0.25 mg/l)
  - Not expected to come into force until December 2022 (will UK adopt?)
  - If not incorporated into UK law there will be no legal imperative on water companies to monitor and control

* hypochlorite generation from brine electrolysis

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Chlorate – New EU MRLs

Reg 2020/749 published 4/6/20

- Came into effect late June 2020
- MRLs for different foodstuffs: 0.01 to 0.7 mg/kg
- Lack of clarity how to apply to e.g. leaf mixed with beetroot

Special case for 'processed' foods:

- In case of exceedance Food Business Operator (FBO) can demonstrate presence to be from legitimate use, i.e. hygiene biocides in e.g. water, washwater, surface disinfection

FBIG submission to HSE (22/5/20) set out:

- Sources of chlorate in food production
- Mitigations in place
- Desired requirement on water industry to mitigate at source and provide data to FBO customers

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What can FBOs do to manage chlorate?

Chlorate is difficult and costly to remove from water

- Reverse osmosis technically viable but expensive
- Granular Activated Carbon filters require maintenance
- Anaerobic digestion has some effect, but is slow
- Ion exchange resins and beds are promising, but specialised technique
- **Water should be treated at source to minimise chlorate**

Supply Chain Quality Assurance by FBOs to verify

- Chlorate not being used as a PPP
- Source of chlorate (hygiene biocides) are being mitigated

If water is chlorinated on-site, e.g. produce washing

- Make up fresh solutions
  - Chlorate salts can settle out – do not top up tanks
  - Tank cleaning/refreshing found to be significant factor in DWI report where chlorate levels were high
- Where Sodium hypochlorite is stored in bulk:
  - Clean the tank
  - Ensure deliveries do not cause mixing resulting in elevated levels of chlorate in suspension
  - Consider any interim-tanks or dead-spots in pipework

Chlorate MRLs Compliance Guidance issued by FBIG 2020 onwards

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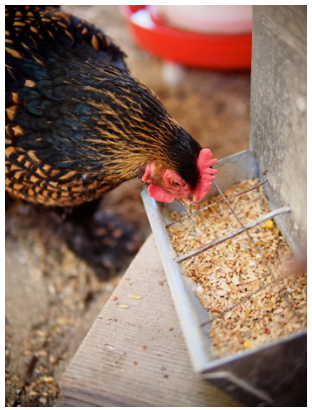
Multicomponent Foods

- **Sandwich as an example**
  - Bread
  - Butter (or margarine)
  - Produce e.g. vegetables, herbs
  - Protein
  - Dressings

- **Sources of biocide traces**
  - Animal feed
  - Water
  - Food contact surface disinfectants and sanitisers



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Bread Manufacture

Grain milling

Flour Silo

Potable water

Other Ingredients

Mixing

Dough Dividing

Rounding

Proving

Moulding

Conveyor to final proving

Proving

Baking

Depanning

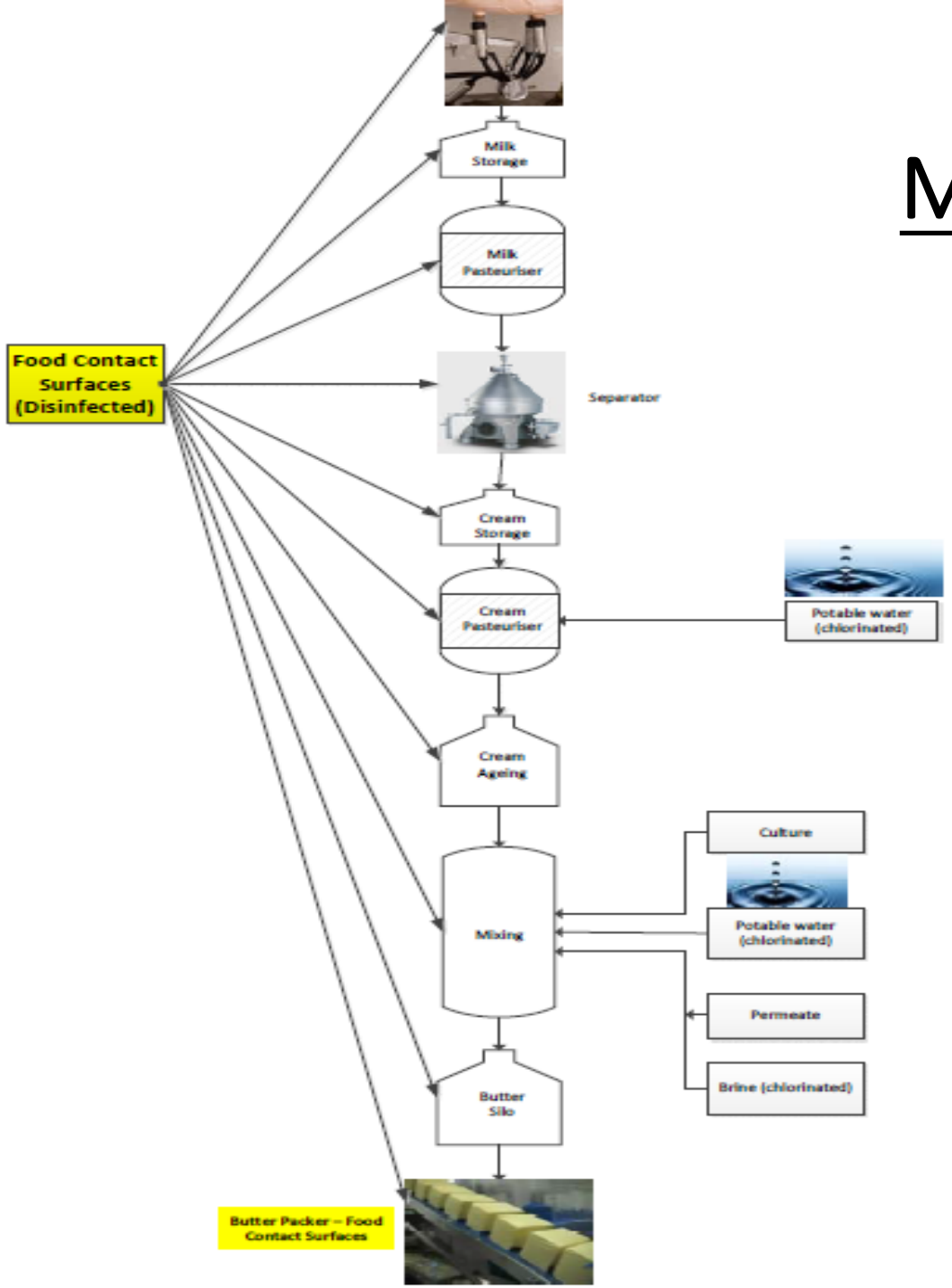
Cooling

Slicing - blades

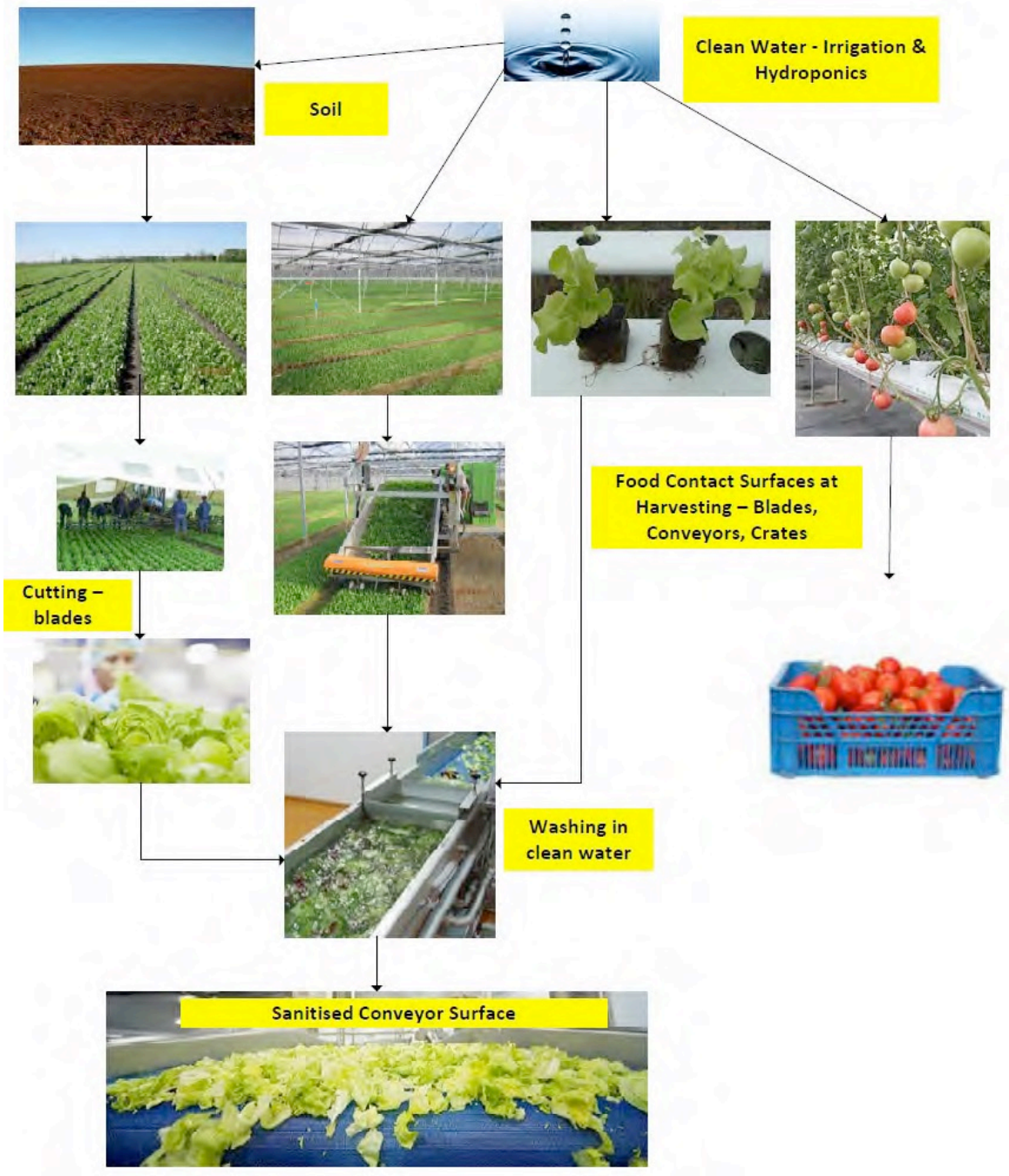
Wrapping

Food Contact Surfaces (Sanitised)

Butter Manufacture

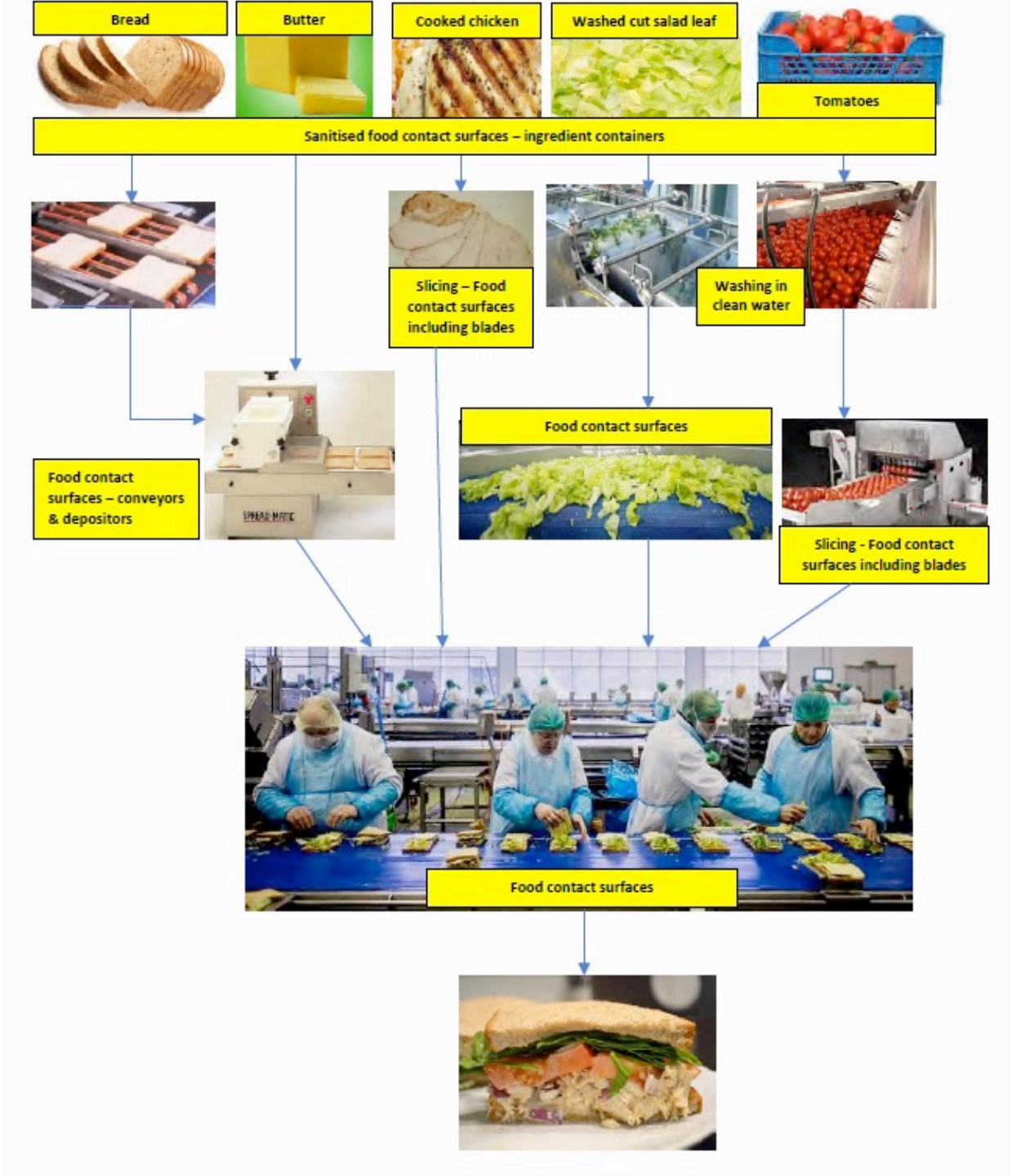


Fresh Produce Components



Protein Components (e.g. Chicken)

Sandwich Manufacture



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What's Next?

Quaternary Ammonium Compounds

- **Quats, QACs (e.g. BAC, DDAC)**
  - Quats highly effective against Gram positive (e.g. *L. monocytogenes*)
  - EU MRL reduced from 0.5ppm to 0.1 ppm on 12/8/15
  - Sales since reportedly dropped by 50%
  - EU review with aim of setting MRLs
  - Review paused summer 2020 owing to
    - Recognition of lobbying showing importance of QACs in food hygiene and SARS-CoV-2 control, and
    - Lack of reliable methodology to determine at levels proposed – issue with isomers

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What Have We Done?

- **Secured**
  - EC recognition of
    - legal requirement and commercial imperative to protect food hygiene and safety and public health
    - primary sources of chlorate
  - More rational EU chlorate MRLs than LOD and those then proposed in Nov 2015
  - Special case in EU chlorate Regs for processed foods
    - Defined as in 852/2004
    - FBO to show on exceedance that came from legitimate uses

- **Developed Guidance (www.chilledfood.org/FBIG)**
  - **Minimising hygiene biocides traces from cleaning and disinfection**
    - Guidance incorporated into Global Food Safety Initiative's *Chemicals in Food Hygiene* (2019)
  - **Chlorate MRLs Compliance**:
    - Multicomponent foods
    - Fresh and prepared produce
    - Cured meat, dried milk, butter
    - Soft drinks and fruit juices
    - Dairy products – in development
    - Specialist nutrition - in development

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What Do We (still) Want?

- **Protect public health**
  - Continued regulatory recognition of food hygiene imperative
- **Rational legislation**
  - Non-pesticide hygiene biocides use not regulated via 396/2005
  - Legislation not gold plated to include end products that are not listed in PPP regulations
  - Multicomponent/processed foods recognised as special case
  - Legislation linkage, e.g. QACs MRLs + food hygiene
- **Chlorate MRL Compliance**
  - FBIG Guidance taken up by UK and EU industry
- **Clear and simple enforcement guidance and rationale**
  - Recognising hygiene requirements and hygiene biocides traces mitigation measures in place

- **Safe, effective and legally viable hygiene biocides leaving minimal traces**

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