



Biotechnological Production

Goods

produced by biotechnological
Production Methods and its
Importance



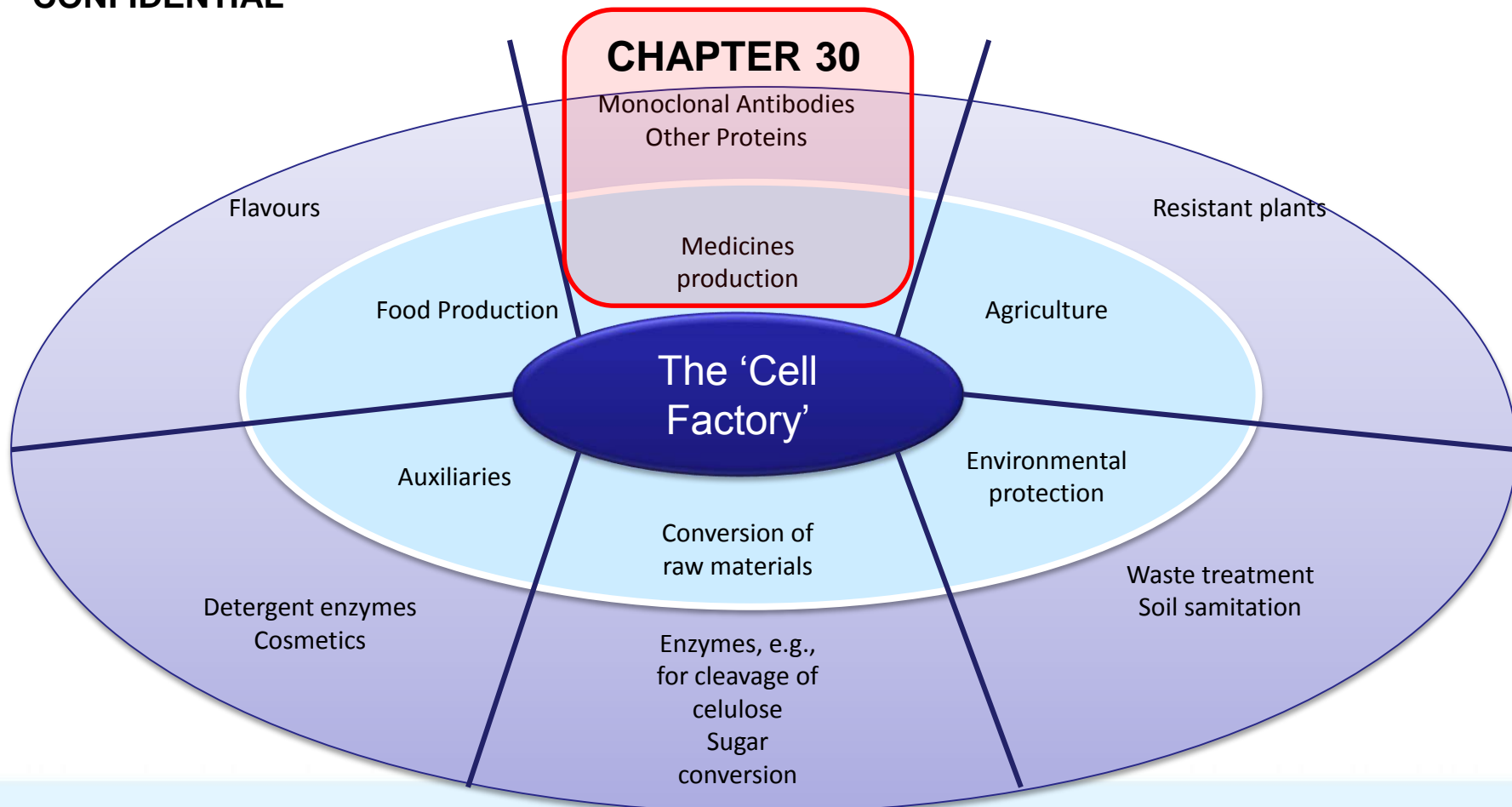
Biotechnology

- Biotechnology is a technology using living organism (such as cells, yeasts, bacteria, fungi) for the production of targeted chemicals and active pharmaceutical ingredients
- Cells are the basic structural, functional and biological unit of all known living organisms
- Cells are grown in cell cultures under controlled conditions, generally outside of their natural environment (highly complex process)



Biotechnology using Cells and Microorganisms as Means of Production in various Industries

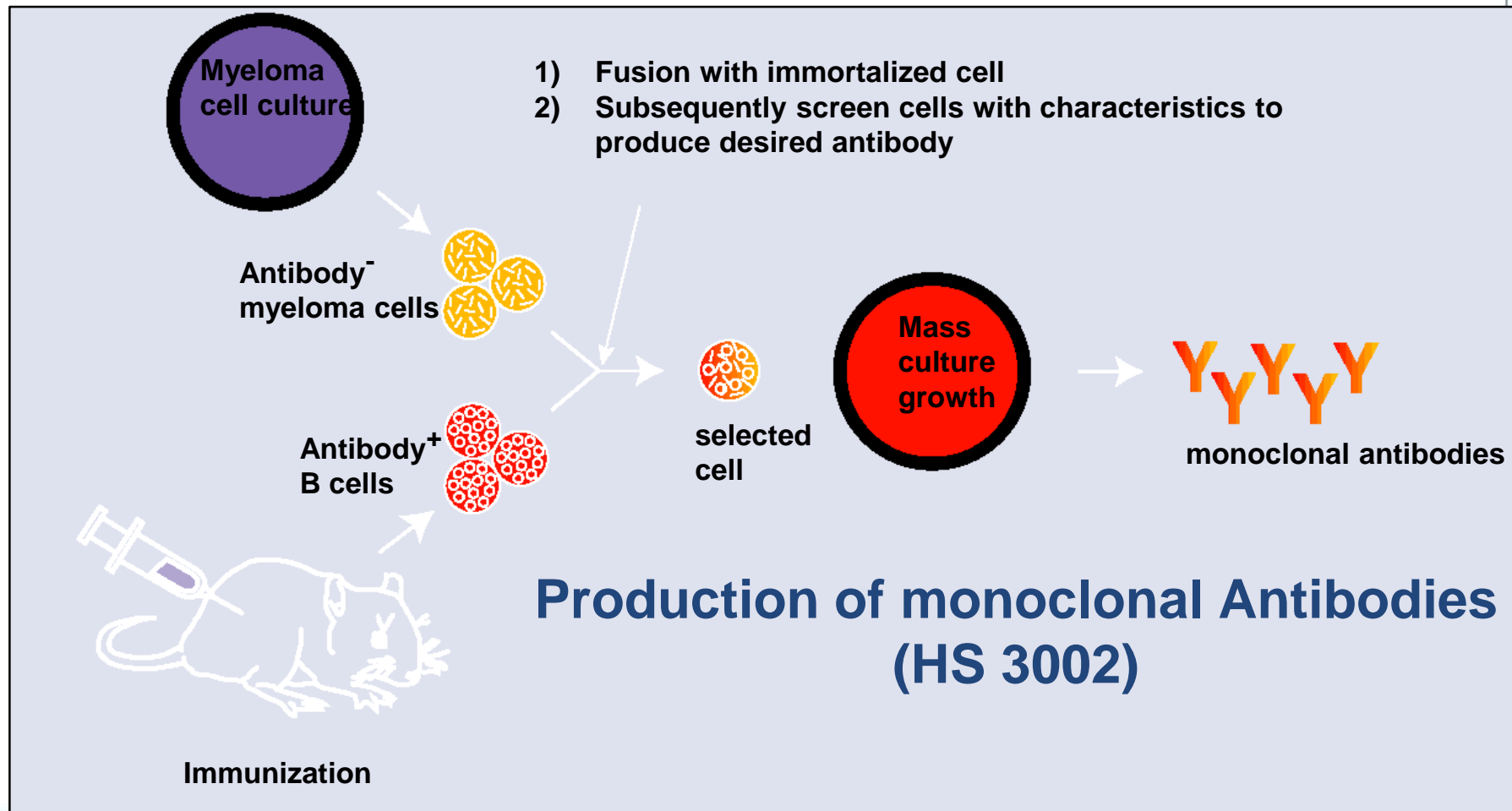
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Focus on the Production of Substances in Chapter 30 3



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Differences

What is different about biotech treatments?

Conventional drugs	Biotech drugs
Normally made by mixing chemicals in a factory	Far more complex, mimicking substances produced by the human body such as enzymes, insulin, and antibodies
They are mostly small, relatively simple molecules and can usually be shaped into a pill and swallowed	Instead of mixing chemicals, biotech drugs are grown in live cells in a bioreactor and then purified. The resulting drugs are almost always administered by injection or infusion
There are around 50 monitoring and quality tests for a traditional (chemical) medicine	Because biotechnology drugs are so complex, the manufacturing of biotechnology-based medicines requires a high level of monitoring and quality testing - typically, around 250 in-process tests are conducted for a biological medicine
Conventional drugs, based on relatively simple molecules, are easy to copy	The unique starting material and the complex manufacturing processes mean that it is more difficult to exactly reproduce a biological molecule in a copy



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Biotech – best selling drugs

Genetic Engineering & Biotechnology News Top 25 Best-Selling Drugs of 2013

2013 Rank	2012 Rank	Drug	Company	Small Molecule/ Biologic
1	1	Humira	AbbVie	Biologic
2	7	Remicade	Johnson & Johnson & Merck & Co.	Biologic
3	3	Rituxan/MabThera	Roche (Genentech) & Biogen Idec	Biologic
4	2	Advair/Seretide	GlaxoSmithKline	Small Molecule
5	11	Enbrel	Amgen & Pfizer	Biologic
6	4	Lantus	Sanofi	Biologic
7	8	Avastin	Roche	Biologic
8	5	Herceptin	Roche	Biologic
9	6	Crestor	AstraZeneca & Shionogi	Small Molecule
10	--	Abilify	Otsuka Pharmaceutical & Bristol-Myers Squibb	Small Molecule
11	9	Cymbalta	Eli Lilly & Shionogi	Small Molecule
12	--	Gleevec/Glivec	Novartis	Small Molecule
13	13	Lyrica	Pfizer	Small Molecule
14	12	Neulasta	Amgen	Biologic
15	--	Copaxone	Teva Pharmaceutical Industries	Biologic
16	--	Revlimid	Celgene	Small Molecule
17	14	Januvia	Merck & Co.	Small Molecule
18	--	Prevnar	Pfizer	Biologic
19	16	Nexium	AstraZeneca	Small Molecule
20	18	Atripla	Gilead Sciences	Small Molecule
21	--	Diovan & Co-Diovan	Novartis	Small Molecule
22	19	Symbicort	AstraZeneca	Small Molecule
23	20	Truvada	Gilead Sciences	Small Molecule
24	--	Novolog/NovoRapid	Novo Nordisk	Biologic
25	--	Avonex	Biogen	Biologic
--	10	Plavix	Sanofi & Bristol-Myers Squibb	Small Molecule
--	15	Lipitor	Pfizer	Small Molecule
--	17	Singulair	Merck & Co.	Small Molecule



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"Fermentation"

The term fermentation has three meanings:

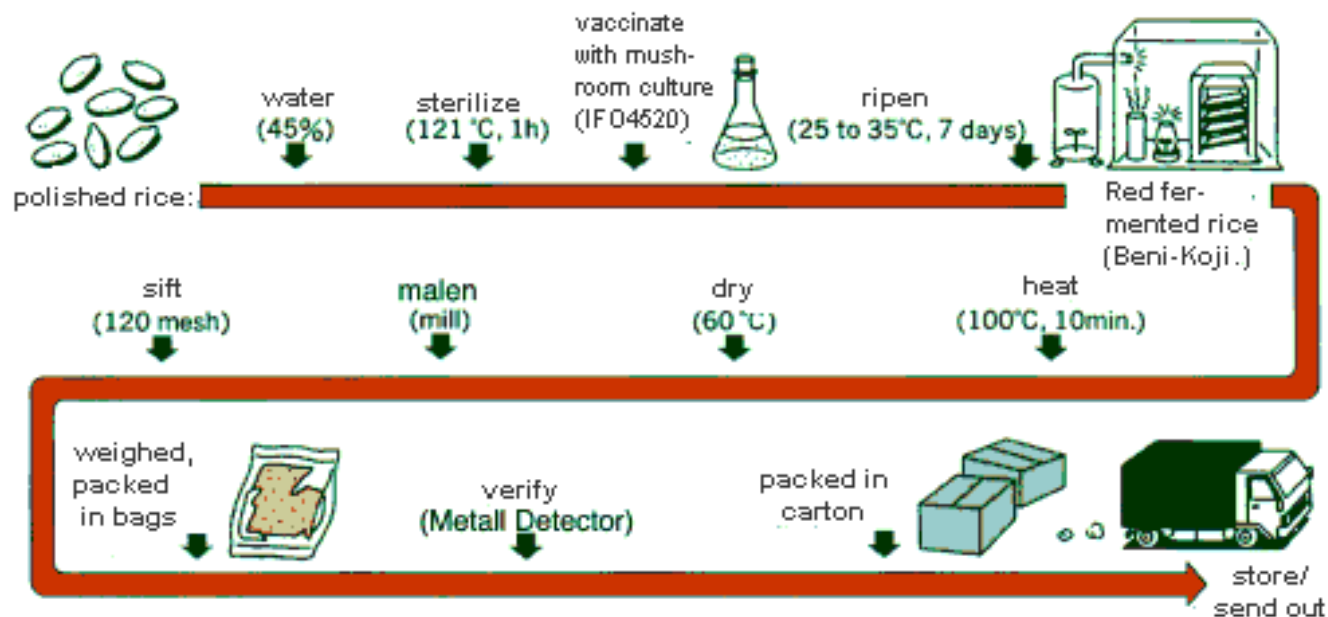
1. In a physiological sense : basis of food fermentation, which is commonly used in the food industry in order to produce diverse food products and also as a food preservation method. (examples: cheese, beer, ...)
2. A process that produces energy by breaking down of energy-rich compounds under anaerobic conditions. (example: production of methane as biogas)
3. In a biotechnological context though, fermentation is used in a much broader sense. There, fermentation means a process in which microorganisms (such as yeasts, bacteria, funghi) that are cultured on a large-scale under aerobic or anaerobic conditions, convert a substrate into a target product. (examples: vitamines, amino acids, ...)



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Example "Fermentation"

- Pigment Production





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Example of "Fermentation"

Product	HS Classification
Lactones	2902, 2905, 2912, 2932
Alcohols (e.g. 2-Phenylethanol)	2907
Vanillin	2912
Esters (e.g. 2-methylbutyl-acetate)	2915
Amino Acids	2922
Organic Acids	2924, 2925, 2933
Vitamines	2936
Insulin	2937
Antibiotics (e.g. Penicilin)	2941

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Example of "Fermentation"

Product	HS Classification
Pigments	32
Flavours and Fragrances	33
Organic surface-active Agents	3402
Biotensides	35
Insecticides, Rodenticides, Fungicides, Herbicides, anti-sprouting Products and plant-growth Regulators	3808
Polyactic Acids (Polyester)	3907



chemical vs. biotechnological production

- Production of Vitamin B2:**

Chemical Production	Biotechnological Production
8 different synthesis Steps	1 Fermentation Step
	40 % Cost Savings
	60% Savings in raw Material
	30% less CO2 Emissions
	95 % less Waste Materials

☺ **biotechnology offers a highly economical and environmental friendly production alternative to the conventional chemical synthesis**



Concept of Biotech in FTAs

- EFTA-Hongkong, China
- EFTA-Central America
- Switzerland-China
- Proposed in all on-going negotiations
- Proposed to implement in existing FTAs



Summary and Proposal

Summary:

Future oriented technologies are already widely used in the production of pharmaceuticals (HS Chapter 30) and other products (within Chapters 29-39) and aligned rules of origin would respect the necessities of the sector concerned.

Proposal:

Products of Chapter 30 obtained by the use of human, plant or animal cell structures and products falling within Chapters 29-39 obtained by fermentation should be considered as originating products.