



Sustaining Innovation and Access in Europe

Nathalie Moll, Secretary General
Brussels, 13 May 2014

European Association of Biotechnology Industries

Three sectors

- **Red: Healthcare biotechnology**
- **White: Industrial biotechnology**
- **Green: Plant biotechnology**

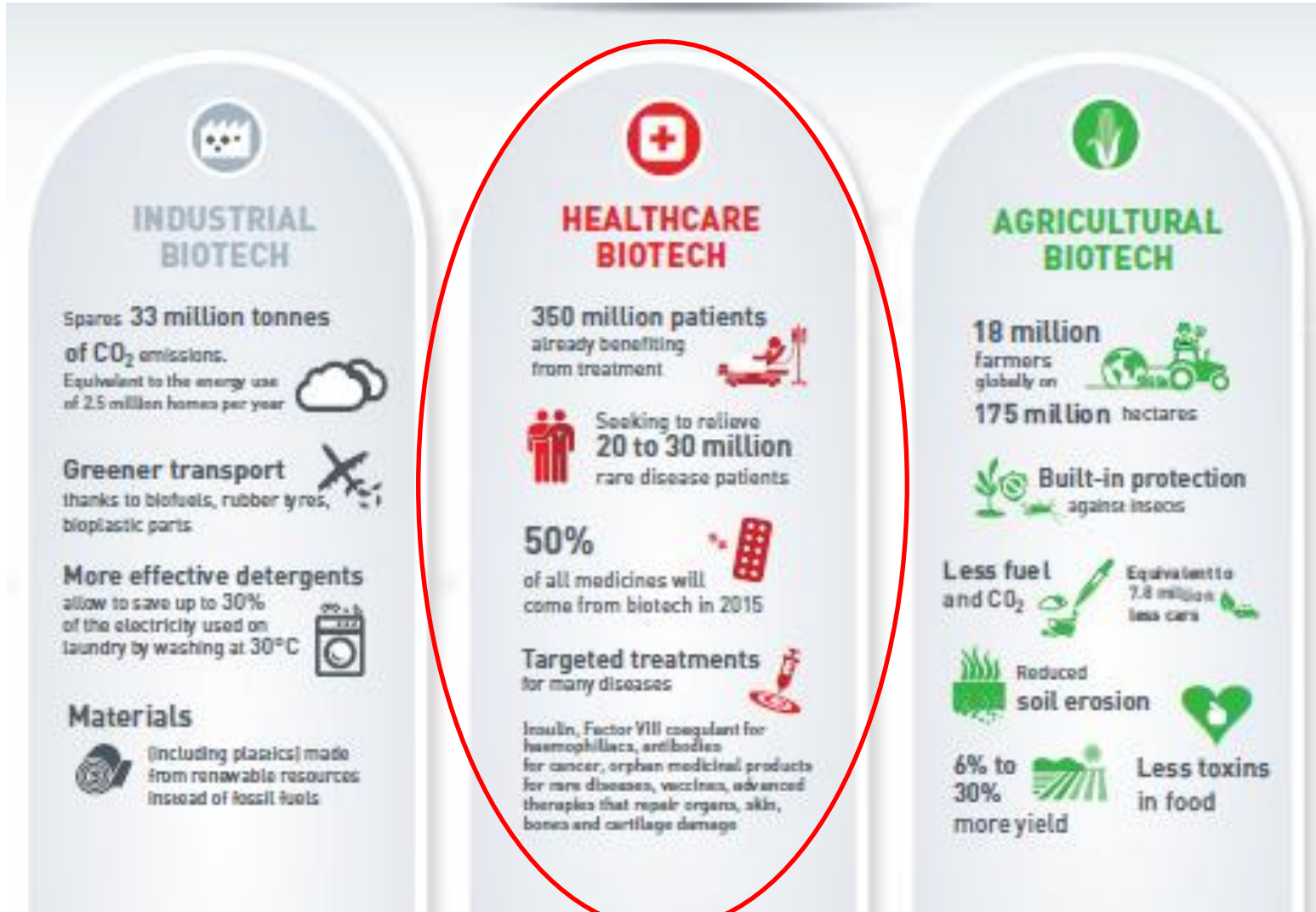
Membership

- **55 corporate members**
- **+15 associate members and 4 Bioregions**
- **+17 National Biotech Associations = +1800 biotech SMEs**

Biotech's contribution in Europe



Biotech's impact per sector



Biotechnology Industry 2014-2019

Manifesto

for the new European Parliament
and new Commissioners

Time to reap
the benefits in Europe



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1. Research and development phase

- EU-funded projects with clear objectives and translation to end products.
- Coordination of Member States research programmes to maximise impact.
- Competitive patent system and data exclusivity to reward innovative European R&D.
- Funding schemes to support biotech SMEs throughout their capital-intensive pathway to commercialisation.
- Support of translational research and proof of concept via Joint Undertakings (e.g. Biobased Industries JU & Innovative Medicines Initiative II).

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2. Assessment and approval phase

- Innovation Principle adopted in EU decision making to avoid innovation being held up by unfounded concerns.
- Adaptive assessment and access frameworks for innovative biological products in the fields of Personalised Medicine, Orphan Medicinal Products and Advanced Therapy Medicinal Products.
- Respect for legislative timelines in the approval process for agricultural biotech products (GMOs).
- Action plan to eliminate the backlog of pending approvals of agbiotech products (GMOs) and deal with legal uncertainty.
- Science-based assessment criteria with sufficient implementation time and no retroactivity.
- Increased rapid risk communication by competent public authorities to counter unfounded concerns.



3. Market access phase

- Fast and equitable citizen access to innovative biotech products & processes in all Member States.
- Fair and sustainable reward systems supporting research and development of biotechnology-derived therapies in Europe.
- Implementation of the European Commission's Bioeconomy strategy and its action plan.
- Public procurement programmes and supportive measures to stimulate the biobased economy.
- Communication of the benefits of biotechnology and the bio-economy with society including consumers, investors, industry, and policy makers via dedicated communication programmes.

Biotechnology in Europe

The tax, finance & regulatory framework and global policy comparison



EY/EuropaBio report - Objective

To identify, for a selected number of European countries, policies on issues such as **taxation**, **regulation** and the **availability of grants** that are designed to help biotechnology SMEs set themselves up and grow in a sustainable way.

Key non EU locations for Biotechnology were also profiled on the increasingly important topic of R&D incentives. The report surveyed 9 comparable markets across North America, Australasia and emerging regions.

Top industry and venture capital stakeholders share their vision for the future of the industry.

Biotechnology in Europe

The tax, finance & regulatory framework and global policy comparison

- ▶ Regulatory overview
- ▶ EU country profile
- ▶ Non EU country profile for key biotechnology centres
- ▶ Outlook for Biotechnology

EY/EuropaBio report - conclusion

- ▶ Europe indeed has the potential to be a world leader in the field of biotechnology.
- ▶ There are already many tax, financial and regulatory incentives for established companies, as well as start-ups operating in Europe. The excellent research base and skilled labor-force on offer throughout many EU Member States is also of great benefit to the biotechnology sector.
- ▶ However more needs to be done by industry and regulatory authorities alike.

Key trends from the report – life cycle

- ▶ **Overall country environment** – tax (rate), legal certainty (treatment of tax item, patent), relationship (tax payer, authority)
- ▶ **Start up** - finance and attracting investors – tax incentives, reduced rates of CGT or interest deductions against personal tax.
- ▶ **More flexibility for tax losses** - surrender against other income, carry back, brought forward unimpeded, continued availability where change in ownership.
- ▶ **Development** - R&D tax credits – flexibility to receive a cash refund or allow as a credit against the group tax payments or other tax heads.
- ▶ **Regulatory environment** – common set of practices for each country - the clinical trials directive, a simplified and efficient regulatory framework.
- ▶ **Planning for the future** - the use of patent/innovation box regimes for long term planning/structuring and creating value.
- ▶ **Indirect tax and customs.**

	Rate	Use of losses	R&D tax credits	Patent/innovation box	Intellectual Property regime	Capital gains tax (CGT)	Other incentives	Incentives — grants/finance support
Austria	25%	Yes — capped at 75% of income	10% to a cap of €1,000,000				6% and 20% training expenses	€200,000 non refundable and €1m loan
Belgium	33% (lower rate 24.25% to 34.5% up to €322,550). In addition there is a 3% surtax.	Yes — unlimited carry forward, but no carry back	Investment deduction — 145% of acquisition value of qualifying asset or 21.5% of the depreciation amount. An alternative is the R&D credit — investment deduction multiplied by the tax rate.	Yes - 80% of gross income, maximum effective tax rate 6.8%	Yes	CGT rollover relief available in certain cases. No CGT on shares save for a separate assessment of 0.412% subject to conditions	An 80% exemption from wage withholding tax for qualified personnel (eg. researchers) is also available.	Several grants and subsidies available on regional and European level
Denmark	24.5% Reducing to 23.5% in 2015, 22% for 2016 and onwards	Restrictions on carry forward — Offset in full up to DKK7.5m, 60% above DKK7.5m	100% deduction for qualifying expenditure. Tax credit for R&D activities enables a refund of negative tax (loss). The tax credit is calculated as up to 25% of DKK 5m (2015; up to DKK 25m)			Exemption for group shares, subsidiary shares, own shares and unlisted portfolio shares		
France	33.33%	Yes — limit €1m, plus 50% of taxable profits exceeding the limit	30% up to €100m and 5% for qualifying expenses in excess of €100m		15% rate — amortization and financing cost allowed	Young Innovation Enterprise (YIE) — CGT exemption		
Germany	Effective rate 15.825% plus municipal (10%–18%)	Yes — limit €1m, plus 60% of taxable profits exceeding the limit	No	No				No repayable cash grants
Hungary	19% and 10% on first €1.7m	Yes — up to 50% of tax base	Double deduction for R&D expenses		50% dispensation for royalty income			VIP cash grant €10m
Ireland	12.5% and 25% (passive)	Yes — full relief	Yes — 25% (effective deduction 37.5%)		Deduction for broadly defined IP		Three year exemption from corporation tax for start up with carry forward of any unused relief beyond the initial three years	Enterprise Ireland €650,000
Italy	31.4%	Yes — up to 80% of tax base	50% tax credit on incremental R&D, within a maximum of €2.5m per year.			Investor relief from CGT where proceeds rolled over into new investment	Investor relief from CGT where proceeds rolled over into new investment	Commissione Nazionale per le Società e la Borsa (CONSOB) Ministero dello Sviluppo Economico (MISE)
Luxembourg	29.22%	Yes	Yes — SME sector for certain costs	Yes, partial income tax exemption of 80% of net income			Yes if certain conditions are met, a range of tax incentives may apply.	Yes, incentives (other than tax incentives) or finance support are available.
The Netherlands	25% and 20% on first €200,000	Yes — carry forward 9 years, carry back one year	R&D tax credit (formerly known as WBSO) of 35% (50% for start ups) of the first €250,000 of the total wage costs for R&D and 14% of the remainder. RDA (Research & Development Deduction) of 60% for R&D costs/expenses.	Effective tax rate of 5%		CGT exemption or rollover available		Several non-tax incentives and grants
Norway	27%	Yes — carry forward indefinitely	Yes — 18% or 20% for Small and Medium sized enterprises (SMEs) — maximum tax credit available is NOK5m			No CGT for non-resident		Innovation Norway
Poland	19%	5 years. Capped at 30% of loss in any one year	Innovation fund — 50% of eligible cost with approval				Exemption from tax in special economic zone	Maximum cash grant available PLN10m
Portugal	23%	Yes — restricted to 70% of taxable profits	32.5% tax credit on qualifying expenses. €1.5/1.8m cap applies in certain circumstances.			Available in certain circumstances	Reduced rate 5%/10%/15% in disadvantage areas	National Strategic Reference Framework (NSRF)
Spain	30% and 25% on first €120,202 where prior year net revenue was less than €10m (group basis).	Yes — for a period of 18 years	Yes — general rate 25% (42% can be achieved)	60% of gross income				Multiple public funding, can achieve €500,000
Sweden	22.00%	Yes — carry forward indefinitely and available in group	Expenses deductible			Yes, available in limited cases	Reduced payroll for employees engaged in research or development for at least 75% of their work time, or 15 hours per month	Proposals to encourage VC and investors
Switzerland	12%–24%	Yes — carry forward 7 years	Capitalised expenditure — write off or amortize	Canton of Nidvalden - effective rate of 8.8%		Yes — in certain circumstances	Tax holiday, 10 years — canton	Swiss National Science Foundation supports for 8,500 researchers annually
United Kingdom	23%, reducing to 21% on 1 April 2014 and 20% on 1 April 2015	Yes — carry forward full relief	Deduction of 225% of qualifying expenditure for small and medium sized enterprises (SME) with a 130% deduction for large companies.	10% rate being phased in over five years (10% will apply from 2017)		Entrepreneurs' Relief — 10% rate for lifetime gains up to €10m	Most dividends likely to be UK tax free	Multiple public funding opportunities including the Biomedical Catalyst

Summary matrix for key tax policy

United Kingdom: Entrepreneurs relief – 10% rate for lifetime gain of up to stg£10million

Ireland: 12.5% tax rate and 25% R&D tax credit

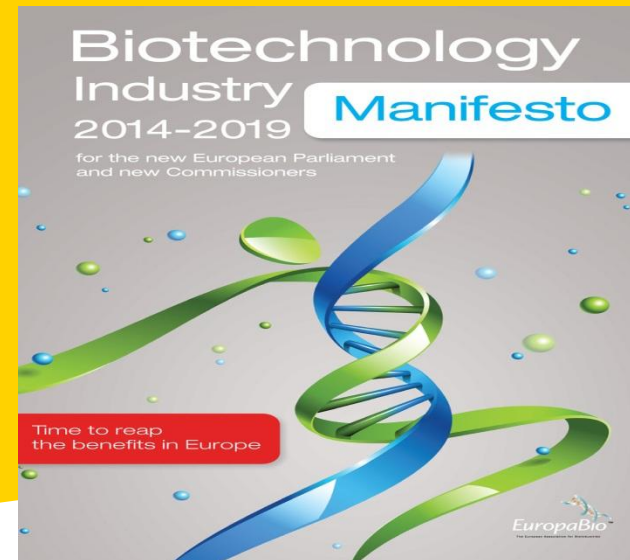
Switzerland: Patent box with effective tax rate 8.8%

EY/EuropaBio report – Social Media



To learn more about Biotechnology in Europe - The tax, finance and regulatory framework and global policy comparison and to see our Biotech Industry Manifesto, please visit:

www.europabio.org





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The European Association for Bioindustries

Thank you for your attention

Nathalie Moll, Secretary General
Brussels, 13 May 2014