

Federal Register of December 30, 2003 (68 FR 75116). The direct final rule amends the biologics regulations by providing options to the existing requirement for separate, dedicated facilities and equipment for work with spore-forming microorganisms. This document confirms the effective date of the direct final rule.

DATES: Effective date confirmed: June 1, 2004.

FOR FURTHER INFORMATION CONTACT:

Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 30, 2003 (68 FR 75116), FDA issued a direct final rule amending the biologics regulations by providing options to the existing requirement for separate, dedicated facilities and equipment for work with spore-forming microorganisms. The regulations were amended due to advances in facility, system, and equipment design and in sterilization technologies that allow work with spore-forming microorganisms to be performed in multiproduct manufacturing areas.

FDA solicited comments concerning the direct final rule for a 75-day period ending March 15, 2004. FDA stated that the effective date of the direct final rule would be on June 1, 2004, unless any significant adverse comment was submitted to FDA during the comment period. FDA received only one comment (from private industry) on the direct final rule. The comment requested FDA to revise § 600.11(e)(4) (21 CFR 600.11(e)(4)), and asked whether this rulemaking affects the interpretation of § 600.11(e)(4). That comment is beyond the scope of this rulemaking, which is not intended to affect the requirements for live vaccine processing set forth in § 600.11(e)(4). FDA has determined that the received comment is not a significant adverse comment.

Authority: Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, the amendments issued thereby become effective on June 1, 2004.

Dated: May 7, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-11027 Filed 5-13-04; 8:45 am]

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PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4022 and 4044

Benefits Payable in Terminated Single-Employer Plans; Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation's regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans prescribe interest assumptions for valuing and paying benefits under terminating single-employer plans. This final rule amends the regulations to adopt interest assumptions for plans with valuation dates in June 2004. Interest assumptions are also published on the PBGC's Web site (<http://www.pbgc.gov>).

DATES: *Effective Date:* June 1, 2004.

FOR FURTHER INFORMATION CONTACT:

Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202-326-4024. (TTY/TDD users may call the Federal relay service toll-free at 1-800-877-8339 and ask to be connected to 202-326-4024.)

SUPPLEMENTARY INFORMATION: The PBGC's regulations prescribe actuarial assumptions—including interest assumptions—for valuing and paying plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions are intended to reflect current conditions in the financial and annuity markets.

Three sets of interest assumptions are prescribed: (1) A set for the valuation of benefits for allocation purposes under section 4044 (found in Appendix B to Part 4044), (2) a set for the PBGC to use to determine whether a benefit is payable as a lump sum and to determine lump-sum amounts to be paid by the PBGC (found in Appendix B to Part 4022), and (3) a set for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology (found in Appendix C to Part 4022).

Accordingly, this amendment (1) adds to Appendix B to Part 4044 the interest assumptions for valuing benefits for allocation purposes in plans with valuation dates during June 2004, (2)

adds to Appendix B to Part 4022 the interest assumptions for the PBGC to use for its own lump-sum payments in plans with valuation dates during June 2004, and (3) adds to Appendix C to Part 4022 the interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology for valuation dates during June 2004.

For valuation of benefits for allocation purposes, the interest assumptions that the PBGC will use (set forth in Appendix B to part 4044) will be 4.30 percent for the first 20 years following the valuation date and 5.00 percent thereafter. These interest assumptions represent an increase (from those in effect for May 2004) of 0.40 percent for the first 20 years following the valuation date and are otherwise unchanged.

The interest assumptions that the PBGC will use for its own lump-sum payments (set forth in Appendix B to part 4022) will be 3.50 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. These interest assumptions represent an increase (from those in effect for May 2004) of 0.50 percent for the period during which a benefit is in pay status and are otherwise unchanged.

For private-sector payments, the interest assumptions (set forth in Appendix C to part 4022) will be the same as those used by the PBGC for determining and paying lump sums (set forth in Appendix B to part 4022).

The PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect, as accurately as possible, current market conditions.

Because of the need to provide immediate guidance for the valuation and payment of benefits in plans with valuation dates during June 2004, the PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

The PBGC has determined that this action is not a "significant regulatory action" under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. *See* 5 U.S.C. 601(2).

List of Subjects**29 CFR Part 4022**

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 4044

Employee benefit plans, Pension insurance, Pensions.

■ In consideration of the foregoing, 29 CFR parts 4022 and 4044 are amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 128, as set forth below, is added to the table. (The introductory text of the table is omitted.)

Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i ₁	i ₂	i ₃	n ₁	n ₂
* 128	* 6-1-04	* 7-1-04	* 3.50	* 4.00	* 4.00	* 4.00	* 7	* 8

■ 3. In appendix C to part 4022, Rate Set 128, as set forth below, is added to the table. (The introductory text of the table is omitted.)

Appendix C to Part 4022—Lump Sum Interest Rates for Private-Sector Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i ₁	i ₂	i ₃	n ₁	n ₂
* 128	* 6-1-04	* 7-1-04	* 3.50	* 4.00	* 4.00	* 4.00	* 7	* 8

PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

■ 4. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

■ 5. In appendix B to part 4044, a new entry, as set forth below, is added to the

table. (The introductory text of the table is omitted.)

Appendix B to Part 4044—Interest Rates Used to Value Benefits

* * * * *

For valuation dates occurring in the month—			The values of i _t are:					
	i _t	for t =	i _t	for t =	i _t	for t =		
* June 2004	* .0430	* 1-20	* .0500	* >20	* N/A	* N/A		

Issued in Washington, DC, on this 11th day of May 2004.

Joseph H. Grant,

Deputy Executive Director and Chief Operating Officer, Pension Benefit Guaranty Corporation.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0135; FRL-7358-9]

Phosphomannose Isomerase and the Genetic Material Necessary for Its Production in All Plants; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues in or on plant

commodities of phosphomannose isomerase and the genetic material necessary for its production in all plants when applied/used as plant-incorporated protectant inert ingredients. Syngenta Seeds, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues in or on all plant commodities of phosphomannose isomerase and the genetic material